EVALUATION OF THE EFFECTS OF EARLY APPLICATION OF BOTULINUM TOXIN IN PATIENTS WITH A FIRST CEREBRAL VASCULAR EVENT.

NCT ID not yet assigned]

MERIDA, YUCATAN, MEXICO

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I Summary

Theoretical Framework: Cerebrovascular disease is the second leading cause of death worldwide and the leading neurological cause of disability. Damage to the pyramidal tract and the accompanying cortico-reticulospinal fibers results in upper motor neuron syndrome. Spasticity is a positive feature of upper motor neuron syndrome that occurs as a result of alterations in the balance between excitatory and inhibitory signals from the spinal motor neuron pool leading to chronic changes in soft tissue and muscle fiber density. Early detection of risk factors for spasticity and management with botulinum toxin not only reduces this complication but may also improve function and increase patient independence.

Objectives: To evaluate the effects of early application of botulinum toxin in patients with cerebrovascular event.

Material and methods: Patients entitled to the General Regional Hospital No. 1 “Lic. Ignacio García Téllez” IMSS Yucatán Delegation, currently active with a diagnosis of cerebrovascular disease admitted to hospitalization by the Internal Medicine and Emergency services in a period of three years. The sampling will be non-probabilistic, for convenience, and all patients with a diagnosis of stroke hospitalized who meet the inclusion criteria will be included (>18 years, entitled to stroke within the first 7 days of evolution).

Patients will be selected, a first assessment will be carried out by the Rehabilitation service in the first seven days after the onset of the stroke, where the patient will be invited to take part in the study, expressing the reason, intention and structure of the work plan, upon confirming their participation they will sign informed consent and the following will be done:

1. Assignment of a folio number to structure your file.
2. Recording of sociodemographic data.
3. Capturing data obtained through clinical records.
4. Neurological physical examination.

The information will be captured in an Excel 2019 spreadsheet (Microsoft ©, Redmont, Washington) and IBM® SPSS Statistics® version 22 to create the database. The analysis and results presentation plan will comprise two phases: a) Descriptive phase. b) Inferential phase. The results of quantitative variables will be compared with the Student t test for paired samples if their distribution is normal or with the Wilcoxon rank test otherwise. Qualitative variables will be compared with the Chi square test. In all cases, a p value <0.05 will be considered statistically significant.

II Background

CEREBROVASCULAR DISEASE: EPIDEMIOLOGY IN MEXICO AND AT THE HGR No. 1 IN MÉRIDA

Cerebrovascular disease is the second cause of death worldwide and the first neurological cause of disability. It most frequently affects people over 65 years of age. The available literature in Mexico describes that ischemic stroke is the most frequent form of cerebral vascular disease in our country and causes between 50 and 70% of cases (PARRA, 2019), followed by intraparenchymal hemorrhage, subarachnoid hemorrhage, transient ischemic attack and cerebral venous thrombosis. [1,2]

The estimated incidence in Mexico according to the BASID (Brain Attack in Corpus Christi) study (CANTU-BRITO et al, 2010)is 230 cases per 100,000 inhabitants, mainly affecting older adults over 64 years of age. The most important risk factor in our population for suffering a cerebrovascular event is hypertension, followed by diabetes mellitus. Mortality from this condition in Mexico is 28.3 per 100,000 inhabitants. [2]

The typical evolution of a stroke follows an ascending curve with a progressively lower slope. In a patient with a favorable recovery, early improvement is due to the recovery of the penumbra tissue of the periphery of the ischemic area and the resolution of diaschisis (transynaptic failure of surrounding areas). Long-term improvement is attributed to neuronal plasticity. [3] 95% of recovery will have been achieved by the third month after the stroke, with the fastest recovery occurring in the first month and a half (85%). Between the fourth and sixth months the recovery slope is slight, almost plateauing, and from the sixth month onwards there is hardly any improvement. [3,4]

Stroke is characterized by the sudden onset of clinical signs related to the brain site where the injury occurs. Damage to the pyramidal tract and accompanying cortico-reticulospinal fibers results in upper motor neuron syndrome, which includes both positive and negative signs. [4] Positive signs include spasticity and abnormal postures; negative signs include those that have been lost, such as strength and dexterity. Initially, about 80% of all stroke patients experience motor deficits in the contralateral limb(s), i.e., hemiparesis with marked decrease in muscle tone.

SPASTICITY: DEFINITION, PATHOPHYSIOLOGY

Spasticity has been defined as a velocity-dependent increase in muscle tone and represents a motor dysfunction arising from upper motor neuron lesions.

Spasticity is a positive feature of upper motor neuron syndrome that arises as a result of alterations in the balance between excitatory and inhibitory signals from the spinal motor neuron pool leading to chronic changes in soft tissue and muscle fiber density.

The most recent definitions of spasticity include all positive symptoms of upper motor neuron syndrome (increased tendon reflexes, presence of pathological reflexes, clonus, spasms, spastic dystonia and velocity-dependent increased tone) excluding complications (contractures, loss of muscle fibers). [5]

Other motor deficits related to spasticity include abnormal synergies, inappropriate muscle activation, and abnormal muscle coactivation. Spasticity manifests only in muscles at rest, whereas the other related motor impairments arise during activation. [6]

NEUROMECHANICAL CONSEQUENCES OF SPASTICITY

Spasticity can worsen the consequences of weakness. Weakness often leads to immobility. Spasticity-related involuntary muscle hyperactivity and synergistic activation tend to immobilize joints in abnormal positions. In turn, this potentiates the development of tendon shortening and muscle contracture over time, leading to abnormal posture, for example, stereotypical presentations of ankle equinus-varus deformity and clenched fist. [6]

Abnormal posture of a joint can have mechanical effects on other joints through the kinetic chain, particularly in the leg during walking.[6,7]

The severity of muscle hyperactivity can be described using the modified Ashworth scale, the Tardieu scale and the Resistance to Passive Movement Scale (REPAS). [7]

DEVELOPMENT AND EVOLUTION OF SPASTICITY IN RELATION TO TIME

The onset of spasticity is highly variable and may occur in the short, medium or long term after stroke or brain injury. [8]

Electroneuromyography (EMG) studies have shown that reflex-mediated increases in muscle tone peak between 1 and 3 months after stroke. [9,10,11] After 3 months, eventual increases in muscle endurance are attributed to intrinsic changes in the muscles. [11]

Lundstrom et al. in their sample of 49 subjects observed early development of spasticity in 27% of patients at 1 month and 23% at 6 months. [12] Wissel et al. presented a study of 94 subjects without preexisting spasticity after the stroke in which they observed early development of spasticity, with 24.5% within 2 weeks after the stroke and among all subjects who developed spasticity at any time during the course of the study, 98% exhibited spasticity with a median presentation of 6 weeks. [13]

In a meta-analysis, Zeng et al. reported the prevalence of spasticity in relation to the time of evolution of the cerebrovascular event, in the first month of 4-46%, from the first to the third month of 4.16-48%, from 3 to 6 months of 6.3-63% and beyond 6 months of 7.6-46% and the prevalence of patients who developed severe spasticity in 2-2.6% during the first month, 5% from the first to the third month, 8-15.6% in the 6 months after the cerebrovascular event and 12.5%-18% after 6 months. [14]

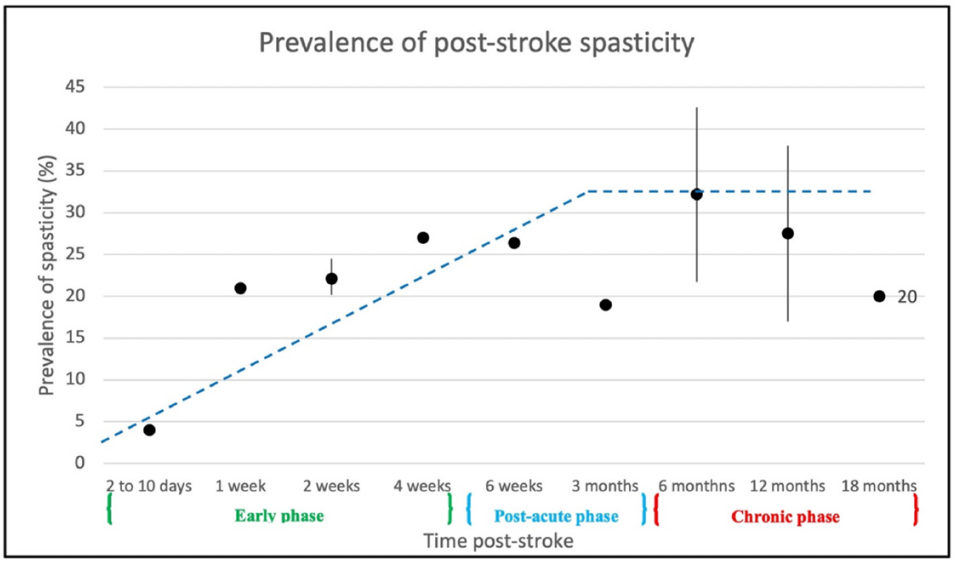

Figure 1. Prevalence of post-stroke spasticity. Image taken from Wissel Jorg et al. [21]

RISK FACTORS FOR THE DEVELOPMENT OF SPASTICITY

Early identification of spasticity, together with the identification of predictors of its onset, allows us to identify patients at higher risk with the aim of initiating early treatment and thereby preventing long-term complications. [15,16]

The SALGOT study evaluated spasticity in the upper limbs following a first stroke, concluding that reduced sensorimotor function was the most important predictor of spasticity at 12 months after the cerebrovascular event and that spasticity could be predicted with high sensitivity at 10 days post-stroke. [17]

Lundström et al. included 49 subjects with any paresis after their first stroke and examined them at baseline (day 2-10 after stroke) and at two follow-up time points, at 1 and 6 months. They assessed muscle tone (assessed by MAS), global disability (assessed by MRS), stroke severity, paresis severity, and sensory disturbance (all assessed by the National Institutes of Health Stroke Scale [NIHSS]). They found that severe arm paresis (more than 2 points on point 5 of the NIHSS) during the first month after stroke was associated with an increased risk of spasticity ($P < 0.001$). All six patients who developed disabling spasticity over the follow-up period had severe initial arm paresis ($P < 0.002$). [12]

Wissel et al. presented a study of 94 subjects without preexisting spasticity who were examined at 6 days post-stroke, 6 weeks, and 16 weeks. At all time points, muscle tone (MAS), pain, paresis, and Barthel Index score were recorded. The presence of hemiparesis correlated with spasticity at the first ($P = 0.02$) and second ($P = 0.005$) follow-up. Hemi-spasticity and increased muscle tone (MAS score ≥1) in more than two joints at 6 weeks, and more severe degrees of paresis at 16 weeks, were risk factors for permanent spasticity. A lower Barthel Index at baseline predicted the development of more severe spasticity at the final follow-up ($P = 0.002$). [13]

Kong et al. investigated patients admitted to a rehabilitation unit after a first-time ischemic stroke (N = 163). They used the Modified Ashworth Scale to assess upper limb spasticity. Upper limb function was assessed and basic activities of daily living were assessed using the Barthel Index. Upper limb spasticity was defined as MAS of 1 or greater. In this sample, upper limb spasticity occurred in 1/3 of patients (54 patients) at 3 months after stroke. As predictive factors, poor upper limb function was the most important factor for the development of moderate to severe spasticity (MAS ≥ 2). [18]

Leitsner et al. conducted a study evaluating patients in the acute phase after stroke (<7 days). Spasticity was assessed with the Resilience to Passive Movement Scale (REPAS) for major joint movements in the upper and lower extremities, according to the Ashworth scale, within 7 days after stroke and at 3 months of progression. Of the 145 patients evaluated with first stroke, 34 patients (23.4%) exhibited spasticity. The Modified Rankin Scale (MRS), the National Institutes of Health Stroke Scale (NIHSS), and the Mini-Mental State Examination (MMSE) were found to be strong clinical predictors of spasticity. The combination of an MRS >2, NIHSS >2, and MMSE <27 showed a positive predictive value (95.2%) for the prediction of spasticity (sensitivity 94.4%, specificity 93.3%). [13]

Opheim et al conducted a study in which they included 117 patients who had experienced a stroke for the first time and with documented arm paresis on day 3 post stroke. Assessments were performed at admission, at 3 and 10 days, 4 weeks and 12 months post stroke. They considered spasticity as an increase in muscle tone assessed through MAS greater than 1, and severe spasticity was considered as MAS greater than 2 in any of the muscles. Sensorimotor function, pain and joint range of motion in the upper limb were assessed with the Fugl-Meyer assessment scale. Demonstrating that spasticity was best predicted with variables collected on day 10 post stroke and severe spasticity was best predicted with variables collected 4 weeks post stroke. The lowest sensorimotor function score, identified with the FMA-UE, consistently and significantly predicted both any spasticity and severe spasticity at 12 months post-stroke. The presence of upper limb spasticity 4 weeks post-stroke was a significant predictor of severe spasticity. [16]

Zeng et al. analyzed 23 studies in a meta-analysis. The incidence of spasticity after first stroke with paresis was 39.5%. The prevalence of disabling or severe spasticity (MAS ≥ 3) in stroke patients with paresis was 9.4%. Mild paresis was defined as NIHSS score less than or equal to 1 on item 5 or 6, or British Medical Research Council (BMRC) scale grade 4, while moderate to severe paresis was greater than or equal to 2 on NIHSS or BMRC grades 0–3. A subgroup of four studies showed that only moderate to severe paresis was a risk factor for spasticity. In subgroup analysis, sensory disturbance was found to predict the development of spasticity in the 3–6 months after stroke, but not at other times. [14]

Nam et al conducted a retrospective study of 861 stroke patients and found that the median time from stroke presentation to presentation of upper extremity spasticity was 34 days. Approximately half of the patients developed spasticity within 1 month after stroke. They concluded that in general, the time of onset of spasticity is 3 days to 6 weeks after stroke, mostly within 1 month. [19]

Table 1. Predictors of post-stroke spastic movement disorder

ACUTE PHASE, FIRST WEEK POST-EVC	POST-ACUTE PHASE
Severe paresis (leading to spasticity within 6 months)	Paresis (leads to spasticity within 6 months)
Low score on the Fugl-Meyer scale (leads to spasticity within 12 months)	Increased muscle tone (leading to spasticity within 12 months)
Increased muscle tone (Ashworth scale greater than 1), leading to spasticity within 3-6 months	Hemiparesis and low Barthel Index score (leads to spasticity within 12 months)
Moderate increase in muscle tone (Ashworth scale greater than 2), leading to spasticity within 3-6 months	Low Barthel Index score + Left paresis (leading to spasticity within 12 months)
Low Barthel Index and EQ-5D scores (leads to spasticity within 3-6 months)	High NIHSS score + Low Motor Index (leads to spasticity within 3 months)
Hemihypoesthesia (leads to spasticity within 6 months)	Extensive lesions on CT or MRI (leading to spasticity within 5 days to 1 year).
High MRS + NIHSS score + low MMST score (leads to spasticity within 3 months)	Severe paresis (leading to spasticity within 12 months)

RATING SCALES

Appropriate assessments for spastic muscle tone, as well as the consequences of post-stroke spastic movement disorder for activities of daily living and motor performance, are well established and include the Ashworth scale (modified), Tardieu scale, active and passive range of motion, Modified Rankin Scale (MRS), National Institutes of Health Stroke Scale (NIHSS), Fugl-Meyer Upper and Lower Extremity Scale, Barthel Index, cognitive tests such as the Mini-Mental State Examination (MMSE). [21]

1.1 NIHSS SCALE (National Institute of Health Stroke Score)

The NIHSS scale numerically scores the severity of stroke. It should be applied at the beginning and during the evolution of the stroke. Minimum score 0, maximum 42 points. It assesses level of consciousness, conjugate gaze, confrontation visual fields, facial paresis, arm paresis, leg paresis, dysmetria, sensitivity, language, dysarthria, neglect.

Ryu et al evaluated 245 patients with the aim of examining the prevalence of spasticity and predictors of the condition. In their evaluation they used the National Institutes of Health Stroke Scale (NIHSS) and found that the score on the scale was significantly predictive of spasticity after a stroke. [20]

Leitsner et al. also managed to highlight the value of applying the scale in predicting the development of spasticity by observing 145 patients during the acute phase of the cerebrovascular event in whom the combination of an MRS >2, NIHSS >2 and MMSE <27 showed a positive predictive value (95.2%) for the prediction of spasticity (sensitivity 94.4%, specificity 93.3%). [13]

1.2 MINI MENTAL STATE EXAMINATION (MMSE)

This is a screening test for dementia, which is also useful for monitoring the disease. It scores a maximum of 30 points and the items are grouped into 5 sections, which include orientation, immediate memory, attention, calculation, delayed recall, language and construction. The cut-off point for dementia is set at 24 points.

1.3 ASHWORTH SCALE

The Ashworth Scale is used to assess tone in neurological patients. It is a qualitative scale and, according to the definition of each of its values, the measurements are ordinal. It is based on the assessment of resistance to passive stretching. The score for this test ranges from 0 (there is no resistance to stretching) to 4 (there is complete resistance).

1.4 MODIFIED TARDIEU SCALE

Scale that assesses spasticity according to the notion of speed as a parameter that participates in the evaluation. First, the maximum angle of joint mobilization is determined, which is obtained at the slowest possible speed (to free oneself as much as possible from the stretch reflex, speed V1). Secondly, the joint is mobilized at the fastest speed possible for the examiner and the angle at which it appears is noted (speed V3). The spasticity angle is the difference between the angle at V1 and the angle at V3. The intensity of the response is indicated on a scale from 0 to 4. The scale retains the reference position of Tardieu, where 0° is the joint amplitude at which the muscle is shortest.

1.5 BARTHEL INDEX

The Barthel Index is a generic measure that assesses the patient's level of independence with respect to carrying out some basic activities of daily living, through which different scores and weights are assigned according to the ability of the subject examined to carry out these activities.

The values assigned to each activity depend on the time spent performing it and the need for assistance to carry it out. The basic activities of daily living included in the index are ten:

eating, transferring between chair and bed, personal hygiene, using the toilet, bathing/showering, moving around (walking on a smooth surface or in a wheelchair), going up/down stairs, dressing/undressing, stool control and urine control. The activities are valued differently, and can be assigned 0, 5, 10 or 15 points. The overall range can vary between 0 (completely dependent) and 100 points (completely independent).

Wissel et al demonstrated that a lower Barthel Index at baseline predicted the development of more severe spasticity at the final follow-up, 16 weeks post-stroke (P = 0.002) [13]

1.6 RANKIN SCALE

The Rankin Scale assesses the patient's functional status and allows for obtaining partial results regarding quality of life (asymptomatic patient, mild, moderate, severe disability or death) since it excludes important assessment items such as mental status or motor functions.

1.7 MEDICAL RESEARCH COUNCIL (MRC) SCALE MUSCLE STRENGTH EVALUATION

The MRC scale is a validated and easy-to-use clinical scale at the bedside, which allows the assessment of muscle strength in 3 muscle groups of each upper and lower limb, in a range from 0 (paralysis) to 5 (normal strength) for each muscle group. The final result obtained ranges from 0 (total paralysis) to 60 (normal muscle strength in all 4 limbs). A value below 48 is considered to define acquired weakness.

1.8 FUGL-MEYER ASSESSMENT SCALE

It is a tool that, through direct observation, evaluates motor performance based on 33 items that are rated from 0 to 2 (0 = cannot do it, 1 = does it partially, 2 = maximum performance). The FMA-EU It takes about 30 min to complete and has a final score ranging from 0 (no functional limitation) to 66 (maximum limitation/disability). This scale has shown excellent reliability and construct validity, and has been validated for use in Spanish (Barbosa et al. 2019). A reduced version of the FMA-UE has recently been implemented, which includes 6 of the original items. This version is quicker and easier to administer and appears to have good psychometric properties (Amano et al. 2020).

1.9 GAS (Goal Attainment Scaling)

It is an individualized, criterion-based measure of change, and its application involves defining a set of unique goals for the patient and then a range of outcomes that reflect specific therapeutic interventions. Kiresuk et al. (1994) strongly recommend the use of scales consisting of five levels of achievement, represented by f scores ranging from -2 to +2. It is

useful for measuring individual goals, functional goals, reflects a patient-centered perspective, and generates a numerical score for analyzing the performance of the multidisciplinary medical team. [23]

THERAPEUTIC OPTIONS AND EARLY INTERVENTION.

Management of PSS includes physical modalities (e.g., stretching, range of motion exercises, ultrasound) (Duncan et al. 2005; Francisco and McGuire 2012) and pharmacologic therapies (e.g., intrathecal and oral baclofen, gabapentin, dantrolene, and botulinum toxins) (Duncan et al. 2005; Thibaut et al. 2013). OnabotulinumtoxinA is a type of botulinum toxin approved for the treatment of upper extremity spasticity in the United States and most regions of the world.

Botulinum toxin A (BoNT-A) has been in clinical use for the treatment of post-stroke spasticity for approximately 30 years and is the accepted standard treatment for post-stroke focal spasticity. [1] BoNT-A treatment is now known to be safe and effective in both upper and lower limb spasticity, where it can result in both active and passive functional gains. [2] Furthermore, BoNT-A is a first-line pharmacological treatment in the management of post-stroke focal and multifocal spasticity, which together with a multidisciplinary team, should be part of a rehabilitation program to promote optimal clinical effect. [10]

BoNT-A has been shown to provide sustained reduction in upper limb spasticity after stroke when combined with rehabilitation in patients as early as 2 to 12 weeks post-stroke (Rosales, Kong et al 2012).

The acute and early subacute phase after the first stroke is a phase of neuroplasticity that allows for effective intervention before maladaptation to severely altered muscle tone and spastic motor pattern, which generate deforming paresis and, in addition, tissue changes. Based on these assumptions, this transition from the early to the late subacute phase after the first stroke marks the boundary for the term "early versus late treatment with BoNT."

In their ONTIME 2018 study Rosales et al investigated whether early injection of abobotulinumtoxinA after stroke delays the onset or progression of upper limb spasticity symptoms. They included 42 patients with a mean time post stroke of 6.18-6.52 weeks. With the application of abobotulinumtoxinA they obtained the greatest statistically significant decrease in tone between weeks 6 and 8 post-application compared to the placebo group who in no assessment between 4-12 weeks post-application achieved statistically significant tone decrease values. [14]

Although the ONTIME study suggests that early injection of abobotulinumtoxinA delays the development of symptomatic spasticity, the effects may not be restorative of maladaptive changes in the brain, due to the finite duration of the treatment effect. However, early treatment may modify disease progression before secondary local biomechanical changes occur. [14]

Picelli et al. conducted a longitudinal, multicenter cohort study in which they aimed to determine whether the time elapsed between the stroke and the initial injection of BoNT-A had an effect on the management of spasticity. They included patients with an evolution time since the stroke of less than 12 months who had spasticity and who had received BoNT-A according to standard clinical practice. They evaluated them at 4, 12, and 24 weeks. They observed that those patients with more than 90 days of disease evolution had higher Ashworth scores at 4, 12, and 24 weeks after the application of the drug compared to patients who underwent surgery less than 90 days after the stroke, suggesting the convenience of starting the management of spasticity with botulinum toxin within 3 months after the presentation of the stroke in order to obtain a greater reduction in muscle tone. [15]

Woo et al conducted a retrospective study in which their primary objective was to compare early versus late use of botulinum toxin for the management of spasticity after the first cerebrovascular event, they included 189 patients who received botulinum toxin within 15 months after the first cerebrovascular event, in 68 of them toxin was applied within the first 12 months of evolution, the mean time of evolution in which the drug was first applied was between 4.7 and 8.6 weeks and for the late application group of 49.6 weeks, they observed that the subsequent application intervals were significantly longer in the early use group (M = 23.1 weeks) compared to the late start group (M = 14.6 weeks) reflecting better control of spasticity in the early start group. [16]

Rosales et al in 2012 conducted a double-blind study with the aim of studying the effectiveness of early use of toxin in patients with upper limb spasticity after a stroke, they included 163 patients of which, 80 were applied toxin and 83 were in the placebo group, all of them were within the first 12 weeks of evolution after the first stroke, they found that the application of toxin achieves a significantly greater decrease in muscle tone assessed by the Ashworth scale at 4 and 24 weeks compared to placebo, they did not observe significant differences in terms of function despite achieving good control of muscle tone, however, the long duration of the effect of the toxin on muscle tone is noteworthy, which could be attributable to the early modification of the changes in the rheological properties of spastic muscles. [17]

These interventions in the early stage of stroke recovery could potentially break the vicious cycle of the interaction of weakness and spasticity and reduce further development of spasticity. [16]

2. METHODS OF APPLICATION OF BOTULINUM TOXIN

Santamato et al. evaluated spasticity in stroke patients after BoNT-A administration to the wrist and finger flexor muscles using ultrasound guidance and surface anatomical landmarks plus palpation. After one month of the treatment session, the patient group treated under

ultrasound guidance reported a statistically significant greater reduction in MAS compared to the group injected using manual needle placement with surface anatomical landmarks plus palpation to identify the target muscles. Ultrasound is well established as a reliable and reproducible imaging method in muscle anatomy. [22]

Picelli and colleagues, comparing three injection techniques for localizing forearm muscles in patients with upper limb spasticity after stroke, showed that instrumental guidance (ultrasound or electrical stimulation) compared with manual needle placement also improved clinical outcomes in these patients one month after injection.

Ultrasound guidance allows injection into the muscles of the forearm, avoiding areas of fat and fibrosis, as well as assessing muscle depth and thickness, reducing the risk of needle insertion above the target thickness. Particularly useful in cases of decreased muscle trophism and for application to small and superficial muscles.

Problem statement:

Stroke is a leading cause of mortality and morbidity in adults in most countries. Spasticity is a common condition in stroke patients.

Spasticity after stroke is often associated with pain, soft tissue stiffness, and joint contracture, and can lead to abnormal limb posture, decreased quality of life, increased treatment cost, and increased caregiver burden. Early detection of risk factors for spasticity and management of post-stroke spasticity not only reduces these complications, but may also improve function and increase independence in patients with spasticity.

This pathology is responsible for a significant health expenditure due to the number of resources used in health services, which is why the disease is considered a priority health problem in our country. In our country, in 2015, just over 21 thousand cases of this disease were registered, and around 5 thousand deaths occurred in the main health institutions. Most of the survivors have moderate to severe sequelae. [5]

Justification

In 2021, stroke in Mexico was the seventh cause of death in the general population, causing 37,453 deaths, the majority in men over 65 years of age, according to data from the National Institute of Statistics and Geography (INEGI). In the world, it is the leading cause of disability in adults.

In our country, there are 118 cases per 100,000 inhabitants, which represents 170,000 new patients per year, of which 20 percent may die in the first 30 days, and seven out of 10 will be left with some disability, with spasticity being one of the most disabling long-term sequelae. [21]

Zeng et al published a meta-analysis in which the prevalence of spasticity ranged from 4% to 46% in the first month, 4.16% to 48% in 1–3 months, 6.9% to 63% in the 3–6 months of onset, and 7.6% to 49% beyond 6 months. 2%–2.6% of patients developed disabling or severe

spasticity within the first month of onset, 5% in 1–3 months, 8%–15.6% in 6 months, and 12.5%–18% beyond 6 months.

Currently, early treatment of PS-SMD in the early subacute phase after stroke is recommended to prevent or reduce the development of post-stroke complications, disability, and improve rehabilitation outcomes.

Research question

What are the effects of early application of botulinum toxin in patients with cerebrovascular events?

HYPOTHESIS.

Ho: Early application of botulinum toxin will have no effect on the development of spasticity in patients with stroke.

Hi: Early application of botulinum toxin will have effects on patients with cerebrovascular events.

GOALS

General objective: To evaluate the effects of early application of botulinum toxin in patients with cerebrovascular event

Specific objectives:

1. To describe the sociodemographic and clinical characteristics of patients with a cerebrovascular event in the first three months of evolution.
2. To identify clinical risk factors that predict spasticity in the first 10 days of a cerebrovascular event.
3. To measure the frequency of spasticity in patients suffering from stroke during the first three months of evolution.
4. Recognize clinical risk factors predicting severe spasticity (MAS greater than 3) in the twelve weeks following the onset of stroke.
5. To describe the short-, medium-, and long-term effects of early application of botulinum toxin plus rehabilitation on muscle tone, functionality, and quality of life in patients who suffer a first cerebrovascular event with a high risk of developing spasticity.
6. To describe the short-, medium-, and long-term effects of early rehabilitation on muscle tone, functionality, and quality of life in patients who suffer a first stroke with a high risk of developing spasticity.
7. To compare the short, medium and long-term effects on muscle tone, functionality and quality of life in patients who suffer a first cerebrovascular event with a high risk of

developing spasticity in the group treated with early rehabilitation and the group to which early application of botulinum toxin is added.

Material and methods:

Following approval by the Local Committee for Research and Ethics in Health Research (CLIES) of the Regional General Hospital Number 1 of the National Medical Center "Ignacio García Téllez" of the IMSS, Mérida, Yucatán, this study will be carried out with the following methodology:

TYPE AND STUDY DESIGN.

This study is a prospective, longitudinal, comparative controlled clinical trial.

Universe of study:

Patients entitled to the Regional General Hospital No. 1 “Lic. Ignacio García Téllez” IMSS Yucatán Delegation, currently active with a diagnosis of cerebrovascular disease admitted to hospitalization by the Internal Medicine and Emergency service of the Regional General Hospital No. 1 “Lic. Ignacio García Téllez”, in a period of three years.

Sample:

The sampling will be non-probabilistic, for convenience, and will include all patients diagnosed with stroke hospitalized in the Internal Medicine and Emergency Department of HGR1 of the Mexican Social Security Institute in Yucatan in a period of three years, who meet the inclusion criteria.

SAMPLE SIZE

It will be a census type and the sample will be determined by the total number of cases, that is, 100% of patients diagnosed with stroke hospitalized on the Internal Medicine and Emergency floor of HGR1 of the Mexican Social Security Institute in Yucatan in a period of three years, who meet the inclusion criteria.

DEFINITION OF OBSERVATION UNITS

Patients diagnosed with stroke hospitalized on the Internal Medicine and Emergency Department of HGR1 of the Mexican Social Security Institute in Yucatan in a three-year period, who meet the inclusion criteria.

Inclusion criteria:

- Men and women ≥18 years old.

- Beneficiaries who are treated in the Emergency and/or Internal Medicine service of HGR N°1, IMSS Mérida Yucatán, affected by an acute stroke with clinical symptoms and a new ischemic lesion in magnetic resonance imaging or computed tomography within 7 days of evolution.

Exclusion criteria:

- Severe cognitive deficits.
- Severe language comprehension disorders.
- Lack of capacity to give informed consent.
- Physical disability already existing before the acute stroke.
- Subarachnoid hemorrhage.
- Transient ischemic attack.
- Any other neurological disorder that could affect muscle tone (Conditions related to the spine, brain infection and traumatic brain injury).
- Any amputation of the limb on the affected side.
- Peripheral neuropathy of upper and/or lower limbs.
- Patients who have suffered a previous stroke.

Elimination criteria

- Death.
- Subsequent assessments are missing.
- Presentation of a second cerebrovascular event.

DEFINITION OF VARIABLES AND UNITS OF EXTENT.

Dependent variables: Functional status, independence in daily living activities, pain, degree of spasticity, muscle stretch reflexes, muscle strength, alteration in superficial sensitivity, cognitive alteration, paresis, motor performance, achievement of goals.

Independent variables: Age, sex, location of the lesion, chronic degenerative history (type 2 diabetes mellitus, systemic arterial hypertension, smoking, heart disease, lung disease, kidney disease, liver disease, neurological disease, metabolic diseases, immunological disease, rheumatological disease), time of evolution, location of the lesion, type of cerebrovascular disease, clinical risk factors predicting spasticity.

Table 1. Operational definition of the variables

Variable	Conceptual Definition	Operational Definition	Indicator	Measuring scale
Functional status	Measuring how well a patient can carry out usual tasks and daily activities.	It will be assessed using the Rankin scale score, which allows obtaining partial results about the patient's quality of life,	Asymptomatic patient Mild disability Moderate disability Severe disability Death	Qualitative nominal

		since it excludes important assessment items such as mental state or motor functions.		
Independence in activities of daily living.	Limitation of health-related attributes that allow a person to be and do what is important to him or her with the affected upper extremity	It is obtained from the total sum of the scores obtained in the Barthel index, to obtain an average value that will be transformed into a final score.	0-100%, a score close to 0% indicates greater dependency	Discrete quantitative
Pain	Unpleasant sensory and emotional experience associated with an actual or potential injury or described in terms of such injury.	A 10-centimeter horizontal line, at the ends of which are the extreme expressions of pain. On the left is the absence or lesser intensity and on the right is the greatest intensity.	0 to 10	Discrete quantitative
Age	Conceptual: time that a person has lived from birth to a certain moment	It will be the age in years recorded in the file.	Number of years	Continuous quantitative
Sex	Conceptual: Set of peculiarities that characterize the individuals of a species, dividing them into male and female.	It will be the sex according to the phenotypic assignment recorded in the file.	Categorized as female or male.	Dichotomous Nominal
Chronic degenerative history	Conceptual: A generally chronic condition during which a continuous process based on degenerative changes in cells takes place , in which the function or structure of the affected tissues or organs worsen over time.	Operational: Presence of chronic degenerative diseases: (Diabetes Mellitus type 2, Systemic arterial hypertension, Smoking, Heart disease) Disease (renal, hepatic, neurological, metabolic, immunological, rheumatological) reported in the file.	But: Type 2 Diabetes Mellitus Systemic arterial hypertension Smoking Heart disease Lung disease Kidney disease Liver disease Neurological disease Metabolic diseases Immunological disease. Rheumatological disease	Dichotomous Nominal
Time of evolution (Duration of stroke)	Conceptual: Time elapsed from the moment of onset of symptoms until a specific moment.	Operational: Time (measured in days) elapsed from the moment of onset of symptoms associated with stroke until the moment of admission to the emergency department.	Number of days	Continuous quantitative
Location of the lesion	Area in the brain where the blood supply to part of the brain is interrupted or reduced, preventing brain tissue from receiving oxygen and nutrients.	Site of the brain that suffers ischemia or hemorrhage, irrigated mainly by one of its three large arteries.	Anterior cerebral artery territory. Middle cerebral artery territory Territory of posterior cerebral artery	Qualitative Nominal
Type of cerebrovascular disease	Cerebrovascular disease is a clinical syndrome characterized by the rapid development of focal neurological signs, which persist for more than 24 hours, with no apparent cause other than vascular origin.	Cerebral ischemia is the consequence of the occlusion of a blood vessel. In intracerebral hemorrhage, the rupture of a vessel results in a collection of blood in the brain parenchyma.	Ischemic/Hemorrhagic	Dichotomous

Degree of Spasticity	Conceptual: Motor disorder characterized by a rate-dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon spasms, as a result of hyperexcitability of the stretch reflex, as a component of upper motor neuron syndrome.	Operational: It will be the presence of alteration of the tone measured on the modified Ashworth scale.	Categorized according to modified Ashworth scale: 0: No increase in muscle tone. 1: Mild spasticity. 2: Moderate spasticity 3: Severe spasticity	Qualitative ordinal
Muscle stretch reflexes (MSR)	Conceptual: Spinal reflex where the skeletal muscle, with intact innervation, is contracted involuntarily, immediately and briefly when a certain tendon is struck.	Operational: It will be the grading of the motor response according to its intensity of the bicipital, tricipital, styloradial, patellar and Achilles muscle stretching reflexes, reported in the note of the first rehabilitation assessment in the patient's electronic file.	Categorized according to REM grading scale: - 0 Normal -1 Decreased response -2Increased response	Qualitative nominal
Muscle strength	Conceptual: It is the result of the manual muscular examination, it is recorded in the form of a numerical score, variable between zero (0), which indicates absence of activity and five (5), which corresponds to a "normal" response.	Operational: It will be the result of the manual muscle examination by muscle groups of shoulder, elbow, wrist, hip, knee and ankle, reported in the note of the first rehabilitation assessment of the patient's electronic file.	Muscle strength grade (0-5) according to Medical Research Council Scale. - Presence of paresis: 0 Absent: total paralysis. 1 Minimal: visible muscle contraction without movement 2 Poor: movement without gravity. 3 Regular: partial movement against gravity only. 4 Good -: complete movement against gravity and minimal resistance. Good: complete movement against gravity and moderate resistance. - Normal/no paresis: 5 Normal: full movement against total resistance.	Qualitative ordinal
Altered superficial sensitivity	Conceptual: Sensitivity, function of the nervous system through which the organism acquires information from the environment around it, having superficial free nerve terminals as receptors.	Operational: It will be the presence of alterations in superficial tactile sensitivity by nerve segments/territories explored by means of a test with an exploration brush or swab, reported in the note of the first rehabilitation assessment in the patient's electronic file.	But	Nominal Dichotomous
Cognitive impairment	Conceptual: Intellectual or cognitive functions.	Operational: It will be the score obtained in the Mini-Mental State Examination (MMSE) test for the evaluation of higher mental	But	Nominal Dichotomous

		functions, reported in the note of the first rehabilitation assessment in the patient's electronic file. The maximum total MMSE score is 35 points. Cognitive impairment is considered to occur with a score less than or equal to 23 points and 27 in geriatric patients.		
Paresis	Decreased strength or absence of voluntary movement.	Decreased strength or lack of movement in upper and/or lower limbs assessed with the NIHSS scale.	Mild paresis was defined as a score of 1 on item 5 and/or 6 of the NIHSS scale. Severe paresis was defined as a score ≥ 2 on item 5 and/or 6 of the NIHSS scale.	Qualitative ordinal
Engine performance	Motor skills aimed at achieving physical and functional independence.	It will be evaluated through direct observation and application of the Fugl-Meyer tool, which has shown excellent reliability and validity and has been validated in Spanish.	0 (no functional limitation) and 66 (maximum limitation/disability)	Continuous quantitative.
Scope of objectives	It is an individualized, criterion-based measure of change, its application involves defining a set of unique goals for the patient and then a range of outcomes that reflect specific therapeutic interventions.	Numerical score obtained by applying the GAS.	-2 Much less -1 A little less 0 Expected result 1 A little more 2 Much more	Nominal qualitative.
Clinical risk factors predicting spasticity	These are parameters, signs and symptoms that appear early and help predict the presence of spasticity in patients who have had a stroke.	Answer to the question: Do you have any clinical risk factors that predict spasticity?	But	Qualitative Dichotomous

METHODS, TECHNIQUES AND PROCEDURES FOR COLLECTING INFORMATION.

Patients who are eligible for the General Regional Hospital No. 1 “Lic. Ignacio García Téllez” IMSS Yucatán Delegation, currently active with a diagnosis of cerebrovascular disease admitted to hospital by the Internal Medicine/Emergency service, will be selected. An initial assessment will be carried out by the Rehabilitation service within the first seven days after the onset of the stroke, where the patient will be invited to take part in the study, expressing the reason, intention, and structure of the work plan, upon confirming their participation they will sign informed consent (Annexes) and the following will be done:

1. Assignment of a folio number to structure your file.
2. Record of sociodemographic data (ANNEXES).
3. Capture of data obtained through clinical records (ANNEXES).
4. Neurological physical examination.
    4.1 Assessment of spasticity

Spasticity will be assessed using the Modified Ashworth Scale (MAS). This is a 6-point ordinal scale with documented reliability. Technique: The patient will be assessed in a resting position. The assessment includes passive flexion and extension movements around the upper joints (shoulder, elbow, wrist, and fingers) and lower extremities (hip, knee, and ankle) performed by a Physical Therapy Resident. Spasticity will be defined as a MAS score ≥ 1 for any of the passive movements performed, in accordance with most previous studies on spasticity after stroke. Moderate spasticity was defined as MAS ≥ 2, and severe spasticity as MAS ≥ 3+.

4.2 Application of Barthel index (ANNEXES).

4.3 Application of Modified Rankin Scale (ANNEXES).

4.4 Application of Mini Mental State Examination (ANNEXES).

4.5 Application of NIHSS Scale (ANNEXES), will be used for the following 3 purposes:

- Assess stroke severity (total NIHSS score).
- To assess the severity of paresis. Severe paresis was defined as a score ≥ 2 on item 5 and/or 6.
- Assess the presence of sensory disturbance, defined as a score ≥ 1 in item 8.

4.6 Muscle strength assessment

The main muscle groups of the upper limbs (shoulder abductors, elbow flexors and wrist extensors) and lower limbs (hip flexors, knee extensors, ankle flexors) will be assessed. The assessment will be made using the Medical Research Council (MRC) scale for the examination of muscle strength, the final result obtained ranges from 0 (total paralysis) to 60 (normal muscle strength in all 4 limbs). Technique:

- The muscle groups involved in 1) shoulder abduction, 2) elbow flexion, 3) wrist dorsiflexion, 4) hip flexion, 5) knee extension, and 6) ankle dorsiflexion will be assessed bilaterally and systematically.
- Each muscle group will be evaluated with a score of 0 to 5 based on the following criteria: Grade 0 No contraction visible or palpable. Grade 1 Mild contraction visible or palpable, although no movement of the limb is observed. Grade 2 Movement performed without weight through all or more than half of the range of motion. Grade 3 Movement against gravity through all or more than half of the range of motion. Grade 4 Movement against mild-moderate resistance through the entire range of motion. Grade 5 Normal contraction power (heavy resistance).
- Muscle assessment will be initiated for an MRC grade of 3 and progressed to grade 2 or 4 depending on the results.
- First, the Resident Physician will reproduce the movement passively and then ask the patient to do the active movement.
- A muscle group will be evaluated bilaterally in order to move on to the next muscle group.

- Up to 3 attempts will be made for each muscle group.
- Rest periods between measurements will be a maximum of 30 seconds unless the patient needs more time to recover.
- The patient will be stimulated to maintain the contraction for 5-6 seconds.

4.7 Application of the Fugl-Meyer Scale for assessing upper and lower limb functionality (ANNEX VII).

6. The patient will be admitted to an intervention group (early neurological rehabilitation vs early neurological rehabilitation + application of botulinum toxin).

7. APPLICATION OF BOTULINUM TOXIN. Patients who meet high-risk criteria for developing spasticity in the first twelve weeks following a first cerebrovascular event will be administered botulinum toxin type A under ultrasound guidance to the affected limbs according to the degree of spasticity.

8. Three subsequent assessments will be carried out to evaluate the development of spasticity and the factors associated with its onset at four, eight and twelve weeks, as well as the early initiation of neurological rehabilitation and the early application of botulinum toxin with subsequent quarterly reassessments until two years after the onset of the cerebrovascular event. Patient recruitment will be carried out at the HGR1 Hospital of the Mexican Social Security Institute in Yucatan over a period of three years, and the follow-up time until the last patient will complete five years in total.

STATISTICAL ANALYSIS

The information will be captured in an Excel 2019 spreadsheet (Microsoft ©, Redmont, Washington) and IBM® SPSS Statistics® version 22 to create the database. The analysis and results presentation plan will comprise two phases:

a) Descriptive phase. Simple frequencies, percentages, measures of central tendency (mean, median and mode) will be calculated for data with abnormal distribution, and dispersion (range, standard deviation) for data with normal distribution, according to the distribution of the variables, using Excel 2019 (Microsoft ©, Redmont, Washington) and IBM® SPSS Statistics® version 22. The description will be complemented with tables and graphs depending on the nature of the variables.

b) Inferential phase. The results of quantitative variables The qualitative variables will be compared with the Student t test for paired samples if their distribution is normal or with the Wilcoxon rank test otherwise. The qualitative variables will be compared with the Chi square test. In all cases, a p value <0.05 will be considered statistically significant.

ETHICAL CONSIDERATIONS.

The design of this study complies with the national and international institutional regulations governing health research, as well as those corresponding to research on human beings. Including the Regulation that establishes the provisions for Health research at the Mexican Social Security Institute 2000-001-009 31; the General Health Law and the Declaration of Helsinki (Fortaleza, Brazil, 2014). According to the regulations of the General Health Law, second title "Ethical Aspects of Research on Human Beings", chapter I, this research protocol is considered as research with greater than minimum risk, since random methods of assignment to therapeutic schemes will be used, for which reason a letter of informed consent will be requested. Annex V The principles of bioethics are respected. It will be considered equitable, since the results obtained in the present study will allow us to guide the management of patients with spasticity due to a cerebrovascular event and guide it in order to better obtain various aspects of their lives. There is justice, since there will be an adequate balance between the investment made and the knowledge obtained. The integrity of the subject is not put at risk, so the principle of non-maleficence is respected. The aim is to obtain results that improve the care of this type of patient (beneficence). The necessary measures will be taken to protect patient data through coding, so as not to identify the name or personal data of patients that may compromise their integrity. The research project will be submitted to the local committee for Research and Ethics of Health Research No. 3401, where it will be evaluated and verified that the necessary criteria are met to be able to carry it out, and if necessary, authorize it.

Human Resources

Physicians and resident physicians in the specialty of rehabilitation medicine qualified to perform ultrasound-guided botulinum toxin application procedures.

Material resources

- Botulinum toxin 100U
- 500 needles 20g
- 800 alcohol swabs
- 2 liters of 70% ethyl alcohol
- 800 syringes of 1 ml
- 300 syringes of 3 ml
- conductive gel
- Marshall portable ultrasound Mod. M9 version 2022 with linear transducer with frequency up to 12-15MHz.
- white sheets

- desktop computer

Feasibility

This study has a high probability of completion because it is a high referral hospital for neurological patients.

Schedule of activities

Year	1st	2nd	3rd	4th	5th	6th
Choice of topic						
Protocol development						
Protocol registration						
Patient identification, application of treatments and assessment.						
Capturing information						
Database development						
Data analysis						
Presentation of results						

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ANNEXES

EXHIBIT YO. CONSENT INFORMED.

MEXICAN INSTITUTE OF SOCIAL SECURITY
EDUCATION, RESEARCH AND HEALTH POLICIES UNIT.
HEALTH RESEARCH COORDINATION.

INFORMED CONSENT LETTER.
(ADULTS)

INFORMED CONSENT LETTER TO PARTICIPATE IN RESEARCH PROTOCOLS.

Study name:	Evaluation of the effects of early application of botulinum toxin in patients with a first cerebrovascular event
Place and date:	HGR No. 1, IMSS, Merida, Yucatan. 2024-2028.
Justification and objective of the study:	To evaluate the effects of early application of botulinum toxin in patients with a first cerebrovascular event.
Procedures:	Patients who have suffered a stroke during the first seven days of their illness and who meet risk factors for developing spasticity will be selected and divided into two groups: one of which will receive botulinum toxin in the affected arm and/or leg plus a rehabilitation program and the other only the rehabilitation program. Assessments will be carried out at four, eight and twelve weeks and subsequently every 3 months.
Possible risks or discomforts	Pain at the application site, muscle or joint pain typical of any rehabilitation exercise program.
Possible benefits you will receive by participating in this study:	Decreased spasticity in the affected body, decreased pain when moving, improved quality of life.
Information on results and treatment alternatives:	The results of each patient will be reported individually to the patient and family.
Participation or withdrawal:	I have been informed that I am free to decide whether or not to participate in this study and that I may withdraw from it at any time without this affecting the care I receive from the Institute.
Privacy and confidentiality:	I was told that my personal data will be encrypted and protected in such a way that it can only be identified by the Researchers of this study or, where appropriate, future studies.

In case of doubts or clarifications related to the study, you can contact:

Principal Investigator:	Dr. Roberto Carlos Pech Argüelles.
Contributors:	Dr. Giovanna Gómez Arredondo, Dr. Jezabel Xitlalic Figueroa Flores, Dr. Omar Eligio

Huchin Cámara, Dr. Abigail Mariela Arriaga Coria, Dr. Maria Eugenia Galindo Gonzalez.

In case of doubts or clarifications regarding your rights as a participant, you may contact: Research Ethics Commission of the CNIC of the IMSS: Avenida Cuauhtémoc 330 4th floor Block “B” of the Congress Unit, Colonia Doctores. Mexico City, CP 06720. Telephone (55) 56 27 69 00 extension 21230, Email: comision.etica@imss.gob.mx

_____	_____
Name and signature of the subject.	Name and signature of the person obtaining consent.
_____	_____
Name and signature of Witness 1	Name and signature of Witness 2

Key: 2810-009-013

ANNEX II. Data collection instrument

Institute Mexican Of the Sure Social (IMSS).
Delegation State Yucatan.
HGR No.1 “Lic. Ignacio Garcia “Tellez”.
Medicine of Rehabilitation.

DATE OF ADMISSION:
FOLIO:

EVALUATION OF THE EFFECTS OF EARLY APPLICATION OF BOTULINUM TOXIN IN PATIENTS WITH A FIRST CEREBRAL VASCULAR EVENT

SHEET OF COLLECTION OF DATA (Instrument of harvest)

Sociodemographic
Name:
Number of security social:
Age:
Sex:
State civil:
Place of residence:
Level of schooling:
Laterality:
Occupation current:
Activity physics either sport:
Activity recreational current:
Phone cellular:
Mail electronic:

Background personal pathological of importance.
Smoking:
Styling:
Hypertension Arterial Systemic (HAS).
Diabetes Mellitus Guy 2 (DM2)
Others pathologies:

Suffering current.
Date of start:
Etiology:
Treatment initial (date, guy and time):
Days of delay in he treatment or Others complications:
CT date: **Type of injury:**

EVOLUTION

- **Symptomatology current.**

Pain	Paresis	Spasticity
Cognitive impairment	Change in sensitivity	Language disorders

- **Exploration physics.**

Weight:	**Size:**	**BMI:**

Complement

- **Variables:**

	Income. / /	**4 weeks.** / /	**8 weeks.** / /	**12 weeks.** / /

Pain (ENA)					
Manual muscle examination of upper and lower limbs (right/left)					
Upper limb	Shoulder flexion				
	Shoulder abduction				
	Elbow flexion				
	Clamp				
Lower limb	Hip flexion				
	Knee extension				
	Ankle flexion				
Trunk control (Yes/No)					

		Income. / /	**4 weeks. / /**	**8 weeks. / /**	**12 weeks. / /**
Upper and lower limb spasticity (right/left). Modified Ashworth Scale					
Upper limb					
	Shoulder abductors				
	Elbow flexors				
	Finger flexors				
Lower limb	**Hip adductors**				
	Knee flexors				
	Ankle plantarflexors				

REMS

	Bicipital	**Tricipital**	**Radial style**	**Patellar**	**Achilles**
Decreased (+)					
Normal (++)					
Increased (+++)					

Barthel Index Score				
Modified Rankin Scale Score				
Mini Mental State Examination Score				
NIHSS Scale Score	**Stroke severity: Severity of paresis: Sensory disturbance:**			
Fugl-Meyer Assessment Scale Score (Upper Extremity)				

NOTAS:

ANNEX III. BARTHEL INDEX

Institute Mexican Of the Sure Social (IMSS). **DATE:**
Delegation State Yucatan. **FOLIO:**
HGR No.1 “Lic. Ignacio Garcia “Tellez”.
Medicine of Rehabilitation.

EVALUATION OF THE EFFECTS OF EARLY APPLICATION OF BOTULINUM TOXIN IN PATIENTS WITH A FIRST CEREBRAL VASCULAR EVENT

Barthel index

Activity	Description	Punctuation
Eat	1. Dependent	0
	2. Needs help cutting, spreading butter, using condiments, etc.	5
	3. Independent (able to use any instrument)	10
Transferring between chair and bed	1. Dependent, does not sit still	0
	2. Requires significant assistance (1 trained person or 2 people), can be seated	5
	3. Needs some help (a little physical help or verbal help)	10
	4. Independent	15
Personal hygiene	1. Dependent	0
	2. Independent for washing face, hands and teeth, combing hair and shaving	5
Using the toilet	1. Dependent	0
	2. Needs some help, but can do something alone	5
	3. Independent (getting in and out, cleaning and dressing)	10
Bathing or showering	1. Dependent	0
	2. Independent for bathing or showering	5
Commute	1. Motionless	0
	2. Independent in wheelchair in 50 m	5
	3. Walks with a little help from a person (physical or verbal)	10
	4. Independent for at least 50 m, with any type of crutch, except a walker	15

Going up and down stairs	1. Dependent	0
	2. Needs physical or verbal assistance, can use any type of crutch	5
	3. Independent for up and down	10
Dressing and undressing	1. Dependent	0
	2. Needs help, but can do about half of it without help	5
	3. Independent, including buttons, zippers, laces, etc.	10
Stool control	1. Incontinent (or requires enema)	0
	2. Exceptional accident (one/week)	5
	3. Continent	10
Urine control	1. Incontinent, or catheterized and unable to change the bag	0
	2. Exceptional accident (maximum one/24 hours)	5
	3. Continent, for at least 7 days	10

INTERPRETATION OF THE BARTHEL INDEX

Punctuation	Classification
<20	Total dependency
21 – 60	Severe dependency
61 – 90	Moderate dependence
91 – 99	Mild dependency
100	Independence

- *Cabañero-Martínez MJ. et al. Arch Gerontol Geriatr. 2009;49(1):e77, PMID: 18990459.*

ANNEX IV. MODIFIED RANKIN SCALE

Institute Mexican Of the Sure Social (IMSS). **DATE:**
Delegation State Yucatan. **FOLIO:**
HGR No.1 “Lic. Ignacio Garcia “Tellez”.
Medicine of Rehabilitation.

EVALUATION OF THE EFFECTS OF EARLY APPLICATION OF BOTULINUM TOXIN IN PATIENTS WITH A FIRST CEREBRAL VASCULAR EVENT

MODIFIED RANKIN SCALE
0. Asymptomatic
1. Without significant disability. Has some symptoms and signs but no limitations in carrying out normal activities or work. Questions: Does the patient have difficulty reading or writing, speaking or finding the right word, problems with stability or coordination, visual disturbances, numbness (face, arms, legs, hands, feet), loss of mobility (face, arms, legs, hands, feet), difficulty swallowing or other symptoms after the stroke?
2. Mild disability The patient has limitations in his/her usual activities and previous work, but is independent in basic activities of daily living (BADL). Questions: Has there been any change in the patient's ability to perform usual activities or work or caregiving compared to before the stroke? Has there been any change in the patient's ability to participate in social or leisure activities? Does the patient have problems with personal relationships with others or has he/she become socially isolated?
3. Moderate disability Needs help with some instrumental activities but not with basic activities of daily living. Walks without help from another person. Needs a caregiver at least twice a week. Questions Do you need help with meal preparation, housekeeping, money management, shopping, or using public transportation?
4. Moderately severe disability Unable to adequately care for self, requiring assistance with walking and basic activities. Requires caregiver at least once a day, but not continuously. May be left home alone for a few hours. Questions: Does he/she require assistance with eating, using the bathroom, daily hygiene, or walking? Could he/she be left alone for a few hours a day?
5. Severe disability. Needs constant attention. Bedridden. Incontinent. Cannot be left alone.
6. Death/Success.

APPENDIX V. MINI MENTAL STATE EXAMINATION (MMSE)

Institute Mexican Of the Sure Social (IMSS).
Delegation State Yucatan
HGR No.1 "Lic. Ignacio Garcia "Tellez".
Medicine of Rehabilitation.

EVALUATION OF THE EFFECTS OF EARLY APPLICATION OF BOTULINUM TOXIN IN PATIENTS WITH A FIRST CEREBRAL VASCULAR EVENT.

MINI MENTAL STATUS EXAMINATION (MMSE)

MINI MENTAL STATUS EXAMINATION[1] **(Folstein et al. 1975)** **CARD NO. 3c**					
Name From the User:		Area:	District:	Type of Care:	
Name of the Care Unit:					
Age	Years:	Months:	Application date:	Applied by:	

ORIENTATION IN TIME	**0**	**1**
What Day is it (date):		
In which month:		
In which year:		
On what day of the week:		
What time is it approximately?		
SCORE (max. 5)		

ORIENTATION IN SPACE		
	0	**1**
Where are we now?		
What floor or apartment are we on now?		
What neighborhood or parish is this?		
What city are we in?		
What country are we in?		
SCORE:(max. 5)		

MEMORY

INSTRUCTION: ***"I am going to tell you the names of three objects. When I finish, I would like you to please repeat them."***

*Pronounce the words clearly, one every second, then ask the older adult to repeat them. Give one point for each correct answer. Repeat the words until the person learns them (max. 6 attempts) but only the first repetition or attempt is scored.

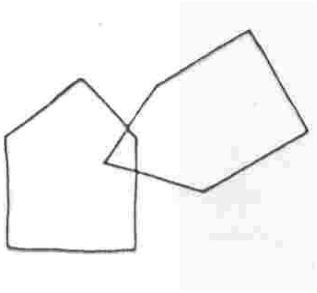
	0	**1**
Paper		
Bicycle		
Spoon		
SCORE: (max. 3)		

ATTENTION AND CALCULATION:		
INSTRUCTION: *"I am going to ask you to subtract 7 at a time starting from 100."*	**0**	**1**
93		
86		
79		
72		
65		

[1] Taken from: Reyes, S., Beaman, P, García-Peña, C., Villa, MA, Heres, J., Córdova, A. and Jagger, C. (2004). Validation of a modified version of the Mini-Mental State Examination (MMSE) in Spanish. Aging Neuropsychology and Cognition, 11, 1-11

	SCORE: (max. 5)	
DEFERRED MEMORY		
INSTRUCTION: *"Tell me the 3 objects I mentioned at the beginning."*	**0**	**1**
Paper		
Bicycle		
Spoon		
	SCORE:(max. 3)	
DENOMINATION	**0**	**1**
Show him a pencil or a pen and ask, "What is this?"		
Show him a clock and ask, what is this?		
	SCORE:(max. 2)	
REPETITION OF A PHRASE		
INSTRUCTION: " *Now I am going to tell you a sentence that you will have to repeat after me. I can only say it once, so pay close attention."*	**0**	**1**
"neither yes, nor no, nor but"		
	SCORE:(max. 1)	
UNDERSTANDING – EXECUTION OF ORDER		
INSTRUCTION: *"I am going to give you some instructions. Please follow them in the order in which I am going to say them. I can only say them once":* *"TAKE THIS PAPER WITH YOUR RIGHT HAND, FOLD IT IN HALF AND LEAVE IT ON THE FLOOR"*		
	0	**1**
Take this paper with your right hand		
Fold it in half		
Leave it on the ground		
	SCORE:(max. 3)	
READING.	**0**	**1**
Write legibly on a piece of paper "close your eyes." Ask the older adult to read it and do what the phrase says.		
	SCORE:(max. 1)	
WRITING.	**0**	**1**
INSTRUCTION: *"I would like you to please write a sentence that conveys a message."*		
	SCORE:(max. 1)	
COPY OF A DRAWING.	**0**	**1**
INSTRUCTION: *"Please copy this drawing as is"*		
	SCORE:(max. 1)	

TOTAL SCORE: (max. 30 points)



EVALUATOR'S SIGNATURE

REFERENCE SCORES:

27-30	**Normal**

24 - 26	**Pathological suspicion**
12-23	**Deterioration**
9-11	**Dementia**

INTERPRETATION OF THE RESULT ACCORDING TO AGE AND LEVEL OF EDUCATION

In the event that this test is applied to elderly people who are illiterate or have a low level of education, the score must be adapted using the following table:

	Age (years)		
Schooling	**Less than 50**	**51-75**	**More than 75**
Less than 8 years of study	0	+1	+2
From 9 to 17 years of study	-1	0	+1
More than 17 years of study	-2	-1	0

* In these cases, what should be done is to take the total score and add or subtract the values indicated in the table taking into account the age and level of education or schooling of the older adult. And then this result is compared with the reference scores. For example:

If the user is 78 years old, has 4 years of education and obtained a final score of 22 points, taking into account what is indicated in the table, 2 points must be added to his final score which would give him a total of 24 points which within the reference scores corresponds to a state of pathological suspicion.

Mini-Mental State Examination (MMSE or Mini-Mental) according to the version by Reyes et al. (2004)

INSTRUCTIVE[2]

REAGENTS	**INSTRUCTIONS FOR ADMINISTRATION**
ORIENTATION IN TIME (5 points) **ORIENTATION IN PLACE (5 points)**	Ask for today's date. Then ask specifically about the omitted data. Score: 1 point for each correct answer
MEMORY (3 points)	Say the three words clearly and slowly, one per second. When you finish, ask for them to be repeated and award one point for each word correctly repeated on the first attempt. When you finish, continue saying them until the patient can repeat them (minimum 3 repetitions, maximum 6). If after six repetitions you still cannot learn them, do not apply the memory.
ATTENTION AND CALCULATION (5 points)	You can use the question “What is 100 minus 7?... minus 7?” etc. to support this question. Avoid mentioning the number from which you are subtracting, i.e. “93 minus 7 or 86 minus 7”, etc., unless it is essential for the test to continue. Give one point for each correct subtraction.
DEFERRED MEMORY (3 points)	Award one point for each word correctly recalled.
DENOMINATION (1 POINT)	Prevent the user from picking up objects unless there is significant visual weakness; try to ensure that information reaches the user only through the visual pathway. One point is awarded for each correctly named object.

[2] Taken from: https://www.villaneuropsicologia.com/uploads/1/4/4/5/14457670/mini_examen_del_estado_mental.pdf

REPETITION OF A PHRASE (1 point)	Say the sentence once, clearly and slowly, but without breaking up the sentence. Grade based on this one attempt. Give one point for correct repetition.
UNDERSTANDING – EXECUTION OF ORDER (3 points)	While giving the command, keep the paper in view of the patient, but do not allow him to take it before you finish giving the commands. Perform only one trial and award one point for each action correctly performed.
READING (1 point)	Award a point only if the older adult performs the action. If he or she only reads the sentence, score 0.
WRITING (1 point)	Use a blank sheet of paper. The sentence must be written spontaneously, do not dictate any sentence. It must contain a subject, verb and predicate. Do not grade spelling.
COPY OF A DRAWING.	10 angles and two intersections must be present. Ignore wobble or rotation.

- Beaman, Sandra Reyes de, Peter E. Beaman, Carmen García-Peña, Miguel Ángel Villa, Julieta Heres, Alejandro Córdova, and Carol Jagger, 2004. "Validation of a modified version of the Mini-Mental State Examination (MMSE) in Spanish." Aging, Neuropsychology and Cognition 11 (1): 1-11. http://doi.org/10.1076/anec.11.1.1.29366

ANNEX VI. NIHSS SCALE

Institute Mexican Of the Sure Social (IMSS).
Delegation State Yucatan
HGR No.1 “Lic. Ignacio Garcia “Tellez”.
Medicine of Rehabilitation.

EVALUATION OF THE EFFECTS OF EARLY APPLICATION OF BOTULINUM TOXIN IN PATIENTS WITH A FIRST CEREBRAL VASCULAR EVENT

NIHSS scale "National Institute of Health Stroke Scale"

1. LEVEL OF CONSCIOUSNESS	
1st. Alert	
Alert with answers normal	0
No alert, but reply to minima stimuli verbal	1
No alert, but reply to stimuli repeated either painful (No highlights)	2
No reply to stimuli painful either only with movements highlights	3
1b. Questions oral Ask he month current and the age. Rate only the first one answer.	
Both answers are correct	0
Only a Answer is correct, IOT, very dysarthric or barrier idiomatic	1
None is correct	2
1c. Orders motor Close - open the eyes and close – open the hand (side No paretic)	
Both answers are correct	0
Only a Answer is correct	1
None is correct	2
2. LOOK CONJUGATED It means that both eyes do the same thing and at rest the eyes are in a central position. Explore only the look horizontal voluntary either with highlights oculocephalic [1] in comatose	
Normal	0
Paresis partial of the look either paresis peripheral of an oculomotor nerve [2]	1
Paresis total either deviation forced of the look conjugated	2
3. FIELDS VISUALS BY CONFRONTATION TO one meter of distance of the patient and cover he eye that is not going to be exploredExplore the upper quadrants and inferior	
Vision No altered	0
Hemianopia [3] partial either visual extinction [4]	1
Hemianopia complete	2
Blindness total	3
4. PARESIS FACIAL Teach the teeth, Yeah No collaborate HE can explore with a stimulus painful	
Motion normal (symmetry of the hemicaras)	0
Minimum asymmetry	1
Paralysis of the area lower of a hemiface	2
Paralysis of the areas lower and superior of a hemiface	3
5. ARM PARESIS First the non-paretic arm Get up and extend he arm to 90º Patient in decubitus, extend he arm to 45º	
5a. Side right	
Maintains the position during 10 seconds, amputation either immobilization	0
Claudica in less of 10 seconds without tap the bed	1
Claudica in under 10 seconds and the tip touch the bed	2
There is motion but No reaches the position either falls immediately	3
Paralysis of the tip	4
5b. Side left ·	
Equal that he side right	

6. PARESIS OF THE LEG First the non-paretic leg Get up the leg extended to 30º	
6a. Side right	
Maintains the position during 5 seconds, amputation proximal either immobilization	0
Claudica in under 5 seconds without tap the bed	1
Claudica in under 5 seconds and the tip touch the bed	2
There is motion but No reaches the position either falls immediately	3
Paralysis of the tip	4
6b. Side left.	
Equal that he side right	
7. DYSMETRIA (Ataxia: incoordination in he motion) Finger-nose and heel-knee, carry out with the eyes open	
Absent, amputation, deficit engine or fusion of the joint	0
Ataxia in a tip	1
Ataxia in two limbs	2
8. SENSITIVITY With needle explore the face, the arms, the trunk, the abdomen and the legs (No hands neither feet)In patient dazed evaluate the withdrawal to stimulus painful	
Normal	0
Mild hypoesthesia (it note)	1
Anesthesia either patient in coma	2
9. LANGUAGE Describe a drawing either read a list of words and phrasesIn patient dumb either IOT explore according to your writing	
Normal	0
Aphasia mild either moderate (can understand)	1
Aphasia serious (No HE can understand)	2
Comprehension null either in coma	3
10. DYSARTHRIA **Appreciate only the joint**	
Normal either IOT	0
Mild either moderate (HE can understand)	1
Serious, unintelligible either dumb	2
11. Extinction and Inattention, Negligence Extinction: in case of stimuli bilateral simultaneous, he patient it's not able to perceive inhe side contralateral to the injury Negligence: he patient is unable of orient either reply in view of a stimulus in he sidecontralateral to the injury Inattention: he patient ignore the stimuli in he side contralateral to the injury	
Without alterations	0
Inattention either extinction in a mode (visual, tactile, space either bodily)	1
Inattention or extinction in further of a mode. No recognizes his ownhand either only recognizes a part from space	2

ANNEX VII. FUGL-MEYER UPPER EXTREMITY ASSESSMENT (FMA-ES)

Institute Mexican Of the Sure Social (IMSS).
Delegation State Yucatan
HGR No.1 “Lic. Ignacio Garcia “Tellez”.
Medicine of Rehabilitation.

EVALUATION OF THE EFFECTS OF EARLY APPLICATION OF BOTULINUM TOXIN IN PATIENTS WITH A FIRST CEREBRAL VASCULAR EVENT

FUGL-MEYER UPPER EXTREMITY ASSESSMENT (FMA-ES)

Assessment of sensorimotor function

TO. TIP SUPERIOR, position seated					
YO. Activity reflects			none.	could be caused	
Flexors : Biceps and flexors of the fingers (to the less one) **Extenders** : Triceps			0 0	2 2	
			Subtotal Yo (max. 4)		
II. Motion volunteer inside of synergies , without aid gravitational			none.	partial	total
Synergy flexor : Hand from knee contralateral untilear ipsilateral. From the synergy extender (adduction of shoulder/rotation internal, extension of the elbow, pronation of the forearm) until the synergy flexor (abduction of the shoulder /rotation external, flexion of the elbow, supination of the forearm).	Shoulder	Retraction	0	1	2
		Elevation	0	1	2
		Abduction (90°)	0	1	2
		Rotation external	0	1	2
	Elbow	Flexion	0	1	2
	Forearm	Supination	0	1	2
Synergy extender : Hand from he ear ipsilateral until the knee contralateral	Shoulder	Adduction/rotation inter	0	1	2
	Elbow	Extension	0	1	2
	Forearm	Pronation	0	1	2
			Subtotal II (max. 18)		
III. Motion volunteer mixing synergies , without compensation			none.	partial	total
Hand to the column lumbar Hand about lap	No can carry out, hand in forehead to thorn iliac antero-superior Hand behind of thorn iliac anterior-superior (without compensation) Hand until the column lumbar (without compensation)		0	1	2
Flexion shoulder 0°-90° Elbow to 0° Pronation-supination 0°	Abduction immediate either flexion of elbow Abduction either flexion of elbow during motion 90° of flexion, No abduction of shoulder neither flexion of elbow		0	1	2
Pronation-supination Elbow to 90° Shoulder at 0°	No pronation/supination, impossible position start Pronation/supination limited, maintains position of start Pronation/supination complete, maintains position of start		0	1	2
			Subtotal III (max. 6)		
IV. Motion volunteer with little either none synergy			none.	partial	total
Abduction of shoulder 0°-90° Elbow at 0° Forearm pronated	Supination immediate either flexion of elbow Supination either flexion of elbow during motion 90° of abduction, maintains extension and pronation		0	1	2
Flexion of shoulder 90°-180° Elbow at 0° Pronation-supination 0°	Abduction immediate either flexion of elbow Abduction either flexion of elbow during motion Flexion of 180°, No abduction of shoulder either flexion of elbow		0	1	2
Pronation/supination Elbow at 0° Shoulder to flexion of 30°-90°	No pronation/supination, impossible position start Pronation/supination limited, maintains position of start Pronation/supination complete, maintains position of start		0	1	2
			Subtotal IV (max. 6)		
V. Reflex activity normal evaluated only Yeah is achieved score total of 6 in Part IV					
Biceps, Triceps, Flexors of fingers	0 points in part IV either 2 of 3 highlights markedly hyperactive 1 reflection markedly hyperactive either to the less 2 highlights energetic Maximum of 1 reflection energetic, none hyperactive		0	1	2
			Subtotal V (max. 2)		

Total TO. TIP UPPER (max. 36)				
B. DOLL HE can give support in he elbow for adopt either keep the position, No support indoll, check range passive of motion before of take test		none.	partial	total
Stability to flexion dorsal of 15° Elbow to 90°, forearm pronated Shoulder to 0°	Flexion dorsal active minor of 15° 15° of Flexion dorsal, No tolerates endurance Maintains flexion dorsal against endurance	0	1	2
Flexion dorsal/volar repeated Elbow to 90°, forearm pronated Shoulder to 0° mild (flexion of the fingers)	No can carry out voluntarily Range of motion asset limited Range of motion asset complete, fluent	0	1	2
Stability to flexion dorsal of 15° Elbow to 0°, forearm pronated Mild flexion/abduction of shoulder	Flexion dorsal active minor of 15° 15° of flexion dorsal, without endurance Maintains position against endurance	0	1	2
Flexion dorsal/volar repeated Elbow to 0°, forearm pronated Mild flexion/abduction of shoulder	No can carry out voluntarily Range of motion asset limited Range of motion asset complete, fluent	0	1	2
Circumduction Elbow to 90°, forearm pronated, shoulder to 0°	No can carry out voluntarily Motion rude either incomplete Circumduction complete and gentle	0	1	2
	Total B (max. 10)			
C. HAND support can be given on the elbow to maintain 90° flexion, no support on the wrist, compare with hand No affected, the objects are interposed, grip asset		none.	partial	total
Flexion in mass	From extension total active either passive	0	1	2
Extension in mass	From flexion total active either passive	0	1	2
GRIP				
to. Grip of hook flexion in IFP and IFD (digits II – V)Extension in MCF II-V	No can carry out Can keep position but weak Maintains position against endurance	0	1	2
b. Adduction of thumb 1st CMC, MCF, IFP to 0°, piece of paperBetween thumb and 2nd joint MCF	No can carry out Can hold paper but No against jerk Can hold paper against jerk	0	1	2
c. Grip guy clamp, opposition Pulpejo of the thumb, against pulp of the 2 dofinger, HE strip either hala he pencil toward above	No can carry out Can hold pencil but No against jerk Can hold pencil against jerk	0	1	2
d. Grip cylindrical Object in shape cylindrical (small can) HE strip either hala toward above with opposition indigits Yo and II	No can carry out Can hold cylinder but No against jerk Can hold cylinder against jerk	0	1	2
and. Grip spherical Fingers in abduction/flexion, thumb opposite, ball of tennis	No can carry out Can hold ball but No against jerk Can hold ball against jerk	0	1	2
	Total C (max. 14)			

ASSESSMENT OF FUGL-MEYER LIMB LOWER (FMA-EI)

Assessment of the sensorimotor function

AND. TIP LOWER					
I. Activity reflects , position supine			none.	could be caused	
Flexors : Flexors of knee			0	2	
Extenders : Reflection Patellar and Aquilian (to the less one)			0	2	
Subtotal Yo (max. 4)					
II. Motion volunteer inside of synergies , position supine			none.	partial	total
Synergy flexor : Flexion of hip maximum (abduction/rotation external), maximum flexion kneel and joint of ankle (feel tendons distal forensure flexion active of knee)	Hip	Flexion	0	1	2
	Knee	Flexion	0	1	2
	Ankle	Flexion dorsal	0	1	2
Synergy extender : From the synergy flexor until the adduction/extension of the hip, extension of the knee and flexion plant of ankle. HE apply endurance for ensure motion asset, assess motion and strength (compare with he side No affected)	Hip	Extension	0	1	2
		Adduction	0	1	2
	Knee	Extension	0	1	2
	Ankle	Flexion plant	0	1	2
Subtotal II (max. 14)					
III. Motion mixed volunteer with synergies , position sitting, knee to 10 cm of the edge of the chair/bed			none.	partial	total
Knee flexion from knee extendedactive either passively	No motion asset		0		
	Flexion No active minor of 90°, feel tendons hamstrings			1	
	Flexion active further of 90°				2
Dorsal flexion of ankle Compare with side No affected	No motion asset		0		
	Flexion dorsal limited			1	
	Flexion dorsal complete				2
Subtotal III (max. 4)					
IV. Motion volunteer with little either no synergy , position of foot, hip to 0°			none.	partial	total
Knee flexion at 90°Hip at 0°, can hold on to balance	Motion No asset either immediate, flexion of hip simultaneous		0		
	Flexion of knee of to the less 90° either flexion of hip during motion			1	
	Flexion of knee of to the less 90° without flexion of hip simultaneous.				2
Dorsal flexion of ankle Compare with side no affected	No motion asset		0		
	Flexion dorsal limited			1	
	Flexion dorsal complete				2
Subtotal IV (max.4)					
V. Reflex activity normal position supine, HE evaluate only Yeah HE achieves he score total of 4 points in the first part IV, compare with side No affected			none.	partial	total
Reflex activity Knee flexors, tendon Aquilliano and Patellar	0 points in part IV either 2 of 3 highlights markedly hyperactive		0		
	1 reflection markedly hyperactive either to the less 2 highlights energetic			1	
	Maximum of 1 reflection energetic, none hyperactive				2
Subtotal V (max. 2)					
Total AND: TIP LOWER (max. 28)					

F. COORDINATION/ SPEED position supine, after of a proof with both legs, with the eyes bandaged, bead to the patellaof the leg opposite, 5 times so fast as sea possible.		marked	mild	none
Shaking	To the less 1 motion complete	0	1	2
	Pronounced either unsystematic	0		

Dysmetria	Mild and systematic No dysmetria		1	2
		>6s	2-5s	<2s
Time	To the less 6 sec. Slower that he side No affected 2-5 sec. further slow that he side No affected Less of 2 sec. of difference	0	1	2
	Total F (max. 6)			

H. SENSATION , lower extremity, blindfolded, compare with he side No affected		anesthesia	hypoesthesia Dysesthesia	normal
Touch Gentle	Leg Plant of the foot	0 0	1 1	2 2
		less than ¾ correct or Absence	¾ correct or considerable difference	correct 100% little or none difference
Position Small alteration in the position	Hip Knee Ankle Finger fat of the foot (joint - IF)	0 0 0 0	1 1 1 1	2 2 2 2
	Total H. (max. 12)			

YO. MOTION ARTICULATE PASSIVE, tip lower					**J. PAIN ARTICULATE** during passive movement,tip lower		
compare with side No affected		only few degrees	diminished	normal	severe pain during motion or pain very marked to the end of the motion	some pain	No pain
Hip	Flexion	0	1	2	0	1	2
	Abduction	0	1	2	0	1	2
	Rotation external	0	1	2	0	1	2
	Rotation internal	0	1	2	0	1	2
Knee	Flexion	0	1	2	0	1	2
	Extension	0	1	2	0	1	2
Ankle	Flexion dorsal	0	1	2	0	1	2
	Flexion plant	0	1	2	0	1	2
Foot	Pronation	0	1	2	0	1	2
	supination	0	1	2	0	1	2
Total (max. 20)					**Total** (max. 20)		

AND. TIP LOWER	/28
F. COORDINATION/ SPEED	/6
TOTAL EF (function motorboat)	/34

H. SENSATION	/12
YO. MOTION ARTICULATE PASSIVE	/20
J. PAIN ARTICULATE	/20

ANNEX VII I. GOAL ATTAINMENT SCALE

Mexican Social Security Institute (IMSS).
Yucatan State Delegation
HGR No. 1 “Lic. Ignacio Garcia Tellez”.
Rehabilitation Medicine.

EVALUATION OF THE EFFECTS OF EARLY APPLICATION OF BOTULINUM TOXIN IN PATIENTS WITH A FIRST CEREBRAL VASCULAR EVENT

Setting the objectives

Objective 1: (main)

Objective 2:

Objective 3:

Objective 4:

EVALUATION OF OBJECTIVES IN 5 POINTS

- Puntuación 0 de la escala GAS:
  . El nivel más probable que se puede alcanzar si el paciente recibe el tratamiento previsto.

-2	-1	0	+1	+2
Mucho menos	Un poco menos	Resultado esperado	Un poco más	Mucho más

Aim 1:

-2	-1	0	+1	+2
Mucho menos	Un poco menos	Resultado esperado	Un poco más	Mucho más
Descripción :	*Descripción :*	*Descripción :*	*Descripción :*	*Descripción :*

Aim 2

-2	-1	0	+1	+2
Mucho menos	Un poco menos	Resultado esperado	Un poco más	Mucho más
Descripción :	*Descripción :*	*Descripción :*	*Descripción :*	*Descripción :*

Aim 3

-2	-1	0	+1	+2
Mucho menos	Un poco menos	Resultado esperado	Un poco más	Mucho más
Descripción :	*Descripción :*	*Descripción :*	*Descripción :*	*Descripción :*

Aim 4

-2	-1	0	+1	+2
Mucho menos	Un poco menos	Resultado esperado	Un poco más	Mucho más
Descripción :	*Descripción :*	*Descripción :*	*Descripción :*	*Descripción :*

WEIGHTING OF OBJECTIVES:

Weight = Importance x Difficulty

Importance (for he patient and the family)		Difficulty (evaluated by he equipment)	
None	0	None	0
Little	1	Little	1
Moderately	2	Moderately	2
A lot	3	A lot	3

Aim 1:

Importancia (para el paciente y la familia)		Dificultad (evaluada por el equipo)	
Ninguna	0	Ninguna	0
Poca	1	Poca	1
Moderadamente	2	Moderadamente	2
Mucha	3	Mucha	3

Aim 2:

Importancia		Dificultad	
Ninguna	0	Ninguna	0
Poca	1	Poca	1
Moderadamente	2	Moderadamente	2
Mucha	3	Mucha	3

Aim 3:

Importancia		Dificultad	
Ninguna	0	Ninguna	0
Poca	1	Poca	1
Moderadamente	2	Moderadamente	2
Mucha	3	Mucha	3

Objective 4:

Importancia		Dificultad	
Ninguna	0	Ninguna	0
Poca	1	Poca	1
Moderadamente	2	Moderadamente	2
Mucha	3	Mucha	3