Clinical Effects Of The Intralesional Application Of Incobotulinum Toxin vs Corticosteroid In Patients With Plantar Fascitis .

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I Summary

Theoretical Framework: Plantar fasciitis (PF) is one of the most common pathologies of plantar pain, with relevance due to its location and symptoms, as it makes it difficult for the individual to carry out daily, work and recreational tasks. Its treatment is multiple, which has been widely discussed. There is little evidence on treatment with botulinum toxin (BoNT) and steroids in the short and medium term, on their superiority between them and on other techniques. Both are efficient analgesics and anti-inflammatories , however there is no standardization of their use.

Objectives: To evaluate the clinical effects of intralesional application of incobotulinum toxin vs corticosteroid in patients with plantar fasciitis .

Material and methods: Prospective, experimental, randomized, controlled clinical study; the population will be recruited in the outpatient clinic of the rehabilitation service meeting the inclusion criteria, two randomized study groups will be formed: GROUP A: Patients who accept intralesional infiltration with incobotulinum toxin . GROUP B: Patients who accept intralesional infiltration with dexamethasone.

Both groups will be assessed before application, at 1 month, at 2 and 4 months post intervention. The visual analogue scale (VAS), the American Orthopaedic Foot and Ankle Society (AOFAS) scale and the Foot and Ankle Disability Index (FADI) will be used to assess pain, foot functionality, functional disability index in activities of daily living, in physical activity and measurement of the dorsiflexion arch in 2 visits at the beginning of diagnosis and at 4 months, collecting the variables and establishing a hypothesis analysis to accept or discard normality criteria of the same with tendency and its significance in relation to $p < 0.05$ to establish contrast of the results with parametric or non-parametric variables according to whether or not the hypothesis of normality is discarded.

II Background

PF is defined as a degenerative and inflammatory process resulting from excessive loading of the plantar fascia due to repetitive tension, causing micro-tears of the same, generating tissue granulation, collagen disorganization and inflammation. Its main function is to prevent the collapse of the longitudinal arch of the foot and assist propulsion in the gait cycle (1,2,3).

Study protocols have been revealed worldwide for its effective treatment by means of infiltrations (with few studies reported in Mexico) showing different injection techniques of the plantar fascia including superficial, deep and intrafascial injections , the latter being the most commonly used technique. However, the evidence shows that to date there is no definitive consensus on the most appropriate technique for FP injection(4).

RISK FACTORS

Among the main risk factors are female sex, people aged 40 to 60 years, anatomical alterations such as heel spurs, flat feet, hollow feet, work activities with weight loads such as walking or prolonged standing. In the non-athletic population, there is an increase in the body mass index > 27 kg/m2, kinematic alterations such as decreased range of dorsiflexion movement (since it causes overpronation of the foot and places a greater load on the fascia), sedentary lifestyle, while in the athletic population there is a higher risk in runners and military personnel because it increases the elastic cycle of stretching-shortening causing injuries and generating microtraumas in the fascia (5,6).

EPIDEMIOLOGY:

The exact incidence and prevalence of PF is unknown, but estimates show that approximately 1 million annual patient visits are due to plantar fasciitis (6). It affects 1 in 10 people at some point in their life, representing 15% of medical consultations for foot pain. In Mexico, 30% of the population suffers from it according to the Ministry of Health.

PF occurs at any age but is described with a higher incidence at 40 to 60 years of age, having a greater predilection for females than males, ratio 2:1. Plantar fasciitis is associated with a variety of sports, but is mainly reported in runners, gymnasts, and basketball players (incidence of 5% to 10%) (5,7).

ETIOLOGY:

It is considered multifactorial, which is why multiple therapeutic options have been analyzed. The different treatment modalities can be classified into noninvasive and invasive therapies (8).

PATHOPHYSIOLOGY:

The PF from its origin in the calcaneal tuberosity , extends distally and inserts into the MTP joints and each proximal phalanx of the toes. Functionally it is divided into 3 contiguous bands or bundles: medial, central and lateral, the largest being the central portion. The heel absorbs 110% of body weight when landing on the heel and up to 200% when running. The PF acts as a shock absorber, but its elongation capacity is limited since after 40 years of age , the fat begins to atrophy, with loss of water, collagen and elastic tissue, and the resulting loss of shock absorption in the heel (1).

Therefore, these findings support that PF is a biomechanical overuse condition resulting in degenerative changes at its attachment to the calcaneus originating inflammatory data initially with subsequent degeneration (7).

It is considered a disorder self-limiting , since in 80-90% of cases the symptoms disappear within 10 months. However, this time interval is frustrating for both the patient and the specialist (9).

CLINICAL PICTURE:

Patients with PF typically present with acute pain, a feeling of stiffness that is exacerbated by the first steps in the morning, long periods of standing or sitting. The pain often decreases with ambulation or the beginning of an athletic activity, but then

increases throughout the day as activity increases. In some patients, gait disturbances may occur, creating an antalgic pattern or limp (6).

PHYSICAL EXAMINATION:

In the physical examination, we can identify anatomical alterations such as flat feet, hollow feet (predisposing to risk factors), signs of atrophy of the fat pad, and gait alterations with anti-pain patterns. Palpation of painful points should be performed, usually reproduced in the medial plantar calcaneal tubercle and the path of its three bands. Passive dorsiflexion of the foot and toes can reproduce the pain. The windlass test specifically involves the active reproduction of pain through passive dorsiflexion of the first metatarsophalangeal joint, and is positive if pain is provoked. Pain can also be checked by keeping the patient on tiptoe or heel, that is, performing maneuvers to tighten the plantar fascia. (1,6).

DIAGNOSIS:

Diagnosis is made through careful questioning and clinical signs found during examination.

Diagnostic aids such as imaging studies (radiographs or ultrasound evaluation) are also described, but are not routinely used. Plain radiographs may show soft tissue calcifications or heel spurs (not pathognomonic for PF) on the underside of the heel and to rule out other pathologies, while ultrasound is inexpensive and useful to rule out soft tissue pathology of the heel and measure fascial thickness (>4.0 mm and increasing intensity). Magnetic resonance imaging is often expensive, used to evaluate repetitive causes of pain determined by the finding of thickening of the plantar fascia with increased signal intensity on T2 weighting (6).

DIFFERENTIAL DIAGNOSES:

Differential diagnoses are grouped according to their etiology into neurological, skeletal and soft tissue causes, the most common being soft tissue

causes. It is important to identify these causes because the therapeutic approach is different (see table 1).

Diagnósticos diferenciales del dolor plantar del talón (7).	
Etiología	**Síntomas**
Causas Neurológicas	
Neuritis de Baxter	Ardor en la parte medial del talón.
Atrapamiento del nervio calcáneo medial	Ardor sobre la cara inferomedial del calcáneo.
Síndrome del túnel tarsiano	Parestesia en el tobillo medial que irradia a la cara plantar del pie.
Causas Esqueléticas	
Fractura aguda de calcáneo	Incapacidad para soportar peso, secundaria a un impacto de alta energía.
Tumor óseo	Dolor óseo profundo de predominio nocturno.
Apofisitis calcánea	Dolor en el talón en niñas de 8 a 13 años o niños de 10 a 15 años.
Fractura por estrés del calcáneo	Dolor en el talón de aparición lenta secundario a cargas repetitivas.
Espondiloartropatías	Dolor en el talón en la inserción del tendón de Aquiles.
Causas en tejidos blandos	
Tendinitis de Aquiles	Dolor en cara posterior del tobillo a nivel del maléolo medial.
Tenosinovitis del flexor largo del dedo gordo	Dolor con flexión resistida del dedo gordo.
Rotura de la fascia plantar	Un chasquido o crujido al despegar el pie del suelo o de hacerlo girar seguido de dolor repentino intenso.
Fibroma plantar	Nódulo en la superficie plantar de la porción media del pie.
Tendinitis tibial posterior	Dolor con resistencia a la inversión del pie.

TREATMENT:

Treatment can be divided into non-surgical and surgical. Non-surgical treatment includes the following:

For initial treatment, the American College of Foot and Ankle Surgeons (ACEFAS) recommends tailoring treatment to the patient's symptoms, lifestyle, and activity level because most treatment modalities are not supported by sufficient evidence, including stretching , since previously, protocols emphasized stretching of the Achilles tendon because of the lack of ankle dorsiflexion. However, studies have indicated that specific stretching of the plantar fascia may be more beneficial than simple muscle strengthening (6). Regarding the use of foot orthoses, a recent systematic review and meta -analysis of 19 studies found very low quality evidence for short-term pain reduction or long-term function as was thought due to its function of reducing fascial tension by providing support and reducing foot pronation (6,10).

Regarding bandaging or taping , some studies mention that it helps to fix the axis of the subtalar joint , reduces excessive pronation and corrects foot disorders, however in a study of 5 controlled trials by Van de Water et al. from 2010, it

demonstrated a decrease in pain in one week, but after this, its effectiveness in reducing pain and improving function is reduced (11).

For dry needling, which consists of inserting a fine needle into a myofascial trigger point, decreasing pain by altering the biochemical environment and local blood flow, a meta-analysis by Chunhui He et al. in 2017 showed that it reduces pain in patients with PF, however, it was limited by the inclusion of different techniques and lower quality studies, while ACEFAS does not recommend being for or against this treatment (12,13). For the purpose of keeping the ankle in a neutral position during sleep to prevent triceps surae contractures, the use of night splints is found, however in a prospective randomized study of 116 patients by A Probe et al. mentions that no statistical differences were observed with the presence or absence of a night splint (14,15).

Another useful treatment in PF is extracorporeal shock wave therapy (ESWT) which was first developed in 1990 and is intended to produce vibrations to form neovascularization, increase growth factors and destroy unmyelinated nerve fibers. Currently there is no consensus on the optimal intensity, pulse or modality of the shock wave (6). In a randomized controlled trial of 166 patients by Rachelle Buchbinder et al. in 2002 showed in 166 patients randomized to placebo and ultrasound-guided ESWT that both groups had improvement in heel pain, but there was no benefit at the end of treatment (16).

Regarding the objective treatment of our study, infiltrations are found, including corticosteroids, which are used to reduce pain and inflammation. Some authors have considered it beneficial, as in the meta-analysis by Zonghuan Li et al. in 2014 where he assigned 2 groups of 83 patients with PF, in the first with the ultrasound-guided application of saline solution and in the other group with dexamethasone. The latter had better pain relief at 4 weeks and decreased PF inflammation at 3 months compared to the saline solution group (17). However, complications such as fat pad atrophy and fascia rupture have been described in 2.4% of patients receiving this type of treatment (6).

BoNT has been used to treat many chronic pain conditions and has recently been used in some studies to treat PF. Its mechanisms of action include inhibition of pain peptides from nerve terminals and sensory ganglia, anti-inflammatory, antiglutaminergic effects, and reduction of sympathetic neural discharge. Some studies such as the only one reported in Mexico, in Monterrey Nuevo León by Elizondo- Rodriguez et al in 2013 , prospective, experimental, randomized, double-blind and controlled clinical trial in 36 patients demonstrated the superior effect in the use of toxin by dividing into 2 groups: group A infiltration with toxin (100 IU in each gastrocnemius and 50 IU in soleus), group B infiltration with dexamethasone (2ml diluted in 2ml of 2% lidocaine in fascia insertion) + stretching exercises in both groups, which were evaluated in 6 visits (at the time of diagnosis, at 1, 2, 4 and 6 months post infiltration) and EVA, AOFAS, FADI and Maryland scales were applied, finding no statistically significant difference in the EVA scale between the 2 groups in the first and second visit, until the third visit improvement was shown in the toxin group as well as in the scale of AOFAS and Maryland improved from the 2nd visit. For the FADI, it was similar at the first visit between the 2 groups and during the second visit until the sixth visit it was significant for the toxin group (17).

In the randomized study by Ruiz-Hernández et al. in 2023 in Spain of 59 patients where pain and functionality were evaluated in 4 visits (at the time of diagnosis, the first, third, sixth and twelfth month post infiltration) using the EVA, AOFAS and FAAM scales of 3 groups: group 1 platelet-rich plasma (PRP) infiltration, group 2 toxin infiltration (application in medial gastrocnemius 100 IU and lateral 50 IU and in fascia insertion 50 IU) and group 3 control (mobilizations and stretching). They reported a progressive improvement in pain at 1 month with significant data on the EVA in the BoNT and PRP group, while in the control group improvement was shown after 3 months. The fresh plasma and toxin groups showed improvement on the AOFAS scale at the first month and persisting over time, while in the control group it was observed after 3 months. However, in the toxin group at 12 months there was a slight but non-significant worsening compared to 6 months suggesting that it was due to the loss of effect over time. For the functional improvement of the FAAM scale, it was observed from 3 months onwards and was maintained until 12

months for the toxin and PRP, the latter being superior, but without significant difference. No adverse effects were reported, concluding that the toxin is superior for short-term treatment while plasma was superior in the long term and for conservative treatment it provides a late improvement for pain relief. Regarding epidemiology, the predominance of the female sex was shown at 70% and in overweight patients (3).

In another prospective, randomized, controlled study by Tannaz-Ahadi in 2022 in Iran where the efficacy of ultrasound-guided infiltration of toxin (100 IU flexor digitorum brevis and 50 IU plantar square diluted in 1.5 ml of saline) vs corticosteroid (intralesional in FP insertion 1ml of corticosteroid diluted in 1ml of 0.9% saline) and stretching exercises for triceps surae and gastrocnemius in 35 patients with a clinical diagnosis of FP between 18 and 65 years of age , who were evaluated using the EVA and FAAM scales on 3 occasions, at the time of diagnosis (before the intervention), at 3 weeks, 12 weeks, and 6 months. It was found that in both groups pain and functionality improved after 3 weeks post infiltration . In the toxin group, the EVA and FAAM improved at 3 and 12 weeks, except at 6 months, compared to the corticosteroid group. It was concluded that the effects of the toxin last longer than those of corticosteroids combined with stretching exercises (4).

Surgical treatment is considered when non-surgical treatments have failed. The preferred surgical method is open, percutaneous or endoscopic plantar fasciotomy without inferior calcaneal exostectomy . Possible complications include collapse of the plantar arch and scarring of the incision site (18).

INCOBOTULINUMTOXIN-A TOXIN (INSTITUTIONAL CODE:0100043620101)

BoNT is produced by Clostridium botulinum toxin, a rod-shaped, spore-forming, anaerobic Gram-positive bacterium. The therapeutic application of botulinum toxin began more than two centuries ago, by the German physician Justinus Kerner , who suggested the supposed clinical utility of a toxin extracted from spoiled sausages (botulus , Latin for sausage), which had caused several fatal outbreaks in the kingdom of Württemberg in the late 18th and early 19th centuries.

However, the first documented therapeutic application was in 1977, when Dr. Alan B. Scott injected a purified botulinum toxin into the extraocular muscles to treat strabismus.

BoNT was first approved by the US FDA in 1989. There are currently seven different toxins (A, B, C, D, E, F, and G), but only toxins A and B are currently used for medical purposes. Both have similar effects, although there are slight differences in the mechanism of action. In terms of potency, type A ranks first, followed by type (19).

MECHANISM OF ACTION:

BoNT inhibits the release of acetylcholine from presynaptic vesicles at neuromuscular junctions, resulting in flaccid paralysis in peripheral skeletal musculature and autonomic nerve terminals. Once BoNT enters the bloodstream, its heavy chain is recognized by receptors on the presynaptic membrane and then taken up by endocytosis. The disulfide bridge is subsequently broken and the light chain is released into the cytosol. The light chain cleaves soluble N -ethylmaleimide-sensitive fusion protein-binding protein receptor proteins and thereby inhibits neurotransmitter release into synaptic vesicles.

Chronic inflammation in soft tissues is associated with hyperexcitability of spinal nociceptive neurons (central sensitization). Botulinum toxin A can counteract and inhibit these peripheral and central sensitization processes, thereby modulating the pain resulting from PF. Botulinum toxin A administration has been shown to inhibit substance P release from dorsal root ganglion neurons and stimulated calcitonin gene (CGRP) release from trigeminal ganglion neurons. Studies have also shown that botulinum toxin A can reduce the expression of proinflammatory cytokines such as IL-1b, IL-6, and TNF-a, dampening the inflammatory process and reducing the spread of pain resulting from peripheral stimuli. These reductions in peripheral sensitization and afferent input to the spinal cord from peripheral nerve endings may indirectly decrease the central sensitization process. Botulinum toxin A can also be transported along the axon in a retrograde manner and modulate neuronal activity in the central nervous system through stimulation of inhibitory

gamma-aminobutyric acid (GABA)-A receptors and m-opioid receptors in the spinal cord. All these properties of botulinum toxin A may explain why administration of this toxin can reduce pain in patients with PF (19).

BoNT has a prolonged biological effect in which its therapeutic effect increases (accumulation phase), remains at a plateau for 6 to 10 weeks (plateau phase), and then gradually decreases (wearing off phase) . Exact data on the duration of action of BoNT in humans is scarce, however some studies report that it remains within the range of three to six months, up to one year, with serotype A toxin being reported to have a longer duration compared to the others (20, 22).

PREPARATION METHOD

According to the bibliography of various authors, different types of dilutions have been used for 100 IU of Incobotulinum ; however, the preparation in 1 ml of 0.9% physiological solution has been the most used for infiltration in FP (19,20).

INDICATIONS AND RECOMMENDATIONS:

According to the FDA, some other authorized indications for the use of BoNT are: expression lines on the face, blepharospasm , hemifacial spasm , strabismus, cervical dystonia , migraine, spasticity in upper and lower extremities, detrusor overactivity , sialorrhea, among others. Currently, it covers around 26 indications in about 6 medical specialties and other indications are being investigated (21).

The maximum dose used is much lower than the lethal dose (3000 U in monkeys). Originally, it was also recommended that total doses of BoNT should not exceed about 400 IU per injection series to reduce the risks of antibody formation, however in the study by Dressler et al. 2015 it was shown that, when necessary, total doses of BoNT can exceed 400 IU without risks of antibody formation and systemic adverse effects (21,22).

BoNT concentration and dose may play important roles in the therapeutic and non-therapeutic effects of individual formulations. Incobotulinum with molecular

weight of 150 kD has its own advantages over other formulations. For example, it does not require refrigeration and contains negligible amounts of albumin (protein load of 0.44 ng/100 units). Therefore, the theoretical risk of antibody production against the toxin is lower than other formulations (19).

Currently there is no standardized dose of toxins for the treatment of FP (21).

The adverse effect profile of BoNT is remarkably benign, as BoNT remains at its injection site and does not participate in the body's overall metabolism, thus sparing critical elements to organs of absorption and secretion. Local adverse effects are caused when BoNT spreads from the target tissue to adjacent tissues. Systemic adverse effects occur when relevant amounts of BoNT are distributed with the bloodstream. (22)

INTERACTIONS

Some studies warn against BoNT therapy in the presence of anticoagulation. However, it has recently been shown that BoNT therapy can be performed safely provided that fine injection needles are used. In case of unusual, hitherto undetected underlying hypersensitivity to BoNT therapy , neuromuscular transmission disorders should be considered (22).

III Justification

FP is one of the most frequent pathologies of plantar heel pain with greater relevance because due to its location and symptoms it makes walking and the performance of daily or everyday tasks that necessarily involve performing a support and push phase with the foot difficult, thus decreasing the individual's physical, work and recreational capacity. If not treated properly, it can evolve and affect the functional capacity of people, increasing days of absenteeism and generating a greater demand for medical consultation and treatment services. In addition, FP may require invasive and expensive surgical procedures, such as fasciotomy, which are not accessible to all patients and can generate comorbidities and disabilities.

Therefore, the search for non-surgical therapeutic alternatives, such as the use of intralesional medications , is essential to improve the management of this pathology.

Although the studies published to date have not yet standardized the use of botulinum toxin or corticosteroids, they have shown a significant decrease in pain, improvement in function and VAS, AOFAS and FADI scores. In addition, treatment with BoNT and steroids in the short and medium term is more effective than conservative treatment with the use of orthoses, taping , dry needling and night splints (6,17).

In this context, BoNT is presented as a therapeutic option with greater efficacy and safety than the use of steroids for PF due to its analgesic and anti-inflammatory effect . Therefore, the need to investigate the effectiveness of BoNT is justified . Intralesional in patients with PF in the rehabilitation outpatient clinic of the Regional General Hospital No. 1 of the IMSS-Yucatán, to evaluate its potential as a non-surgical therapeutic alternative and reduce the economic burden associated with conservative and invasive treatments.

IV.- Problem Statement and Research Question

PF is the most common cause of heel pain, affecting approximately 1 million outpatient visits annually worldwide, affecting 1 in 10 people at some point in their lives. This ankle and foot disease can cause pain and functional limitation in patients, however, most patients resolve the condition conservatively, with various non-surgical and surgical therapeutic alternatives available.

Among these alternatives is the use of intralesional BoNT type a or the use of corticosteroids. intralesional , medications available in the hospital's Rehabilitation Medicine service. However, there is little information at the international level about its effects and it is necessary to know its clinical effects in patients with PF who attend the rehabilitation outpatient clinic at the IMSS General Regional Hospital No. 1 in Yucatán, in order to determine its relevance as a therapeutic option and improve the quality of life of patients.

Therefore, the following research question is raised: What are the clinical effects of intralesional application of incobotulinum toxin vs corticosteroid in patients with plantar fasciitis?

V General Objective

To evaluate the clinical effects of intralesional application of incobotulinum toxin vs corticosteroid in patients with plantar fasciitis.

V.1 First Specific Objective

incobotulinum toxin and corticosteroid in the treatment of plantar fasciitis.

V.2 Second Specific Objective

To compare the intensity of pain, dorsiflexion range of motion, foot and ankle functionality, functional disability index in activities of daily living, and physical activity in FP, at the beginning of diagnostic detection, at 4 weeks post infiltration, at two months, and at four months after therapeutic intervention.

VI General hypothesis

Intralesional application of incobotulinum toxin presents a statistically significant improvement in pain, dorsiflexion range of motion, foot and ankle functionality in patients with plantar fasciitis than intralesional application of corticosteroids.

VII Material and Methods

VII.I Design

A sequential, simple randomized clinical trial will be conducted.

VII.II 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 plantar fasciitis, referred to the Physical Medicine and Rehabilitation service in a period of 4 months.

SAMPLE.

Non-probabilistic sampling of consecutive cases of all patients with plantar fasciitis seen in the Physical Medicine and Rehabilitation outpatient clinic of HGR No. 1 of IMSS Yucatán in the four-month period and who meet the selection 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 the patients diagnosed with plantar fasciitis treated in the physical medicine and rehabilitation service of the Regional General Hospital No. 1 of the Mexican Social Security Institute in the four-month period who meet the selection criteria.

DEFINITION OF OBSERVATION UNITS.

Experimental group. Group A for patients who accept intralesional infiltration of incobotulinum toxin and Group B for patients who accept intralesional infiltration with dexamethasone.

Conceptual definition : Group A therapeutic program in which Incobotulinum toxin will be administered to patients with plantar fasciitis.

Operational definition: Program in which the program will be administered 2 ampoules (200 IU) of Incobotulinum toxin , injectable solution presentation 100 IU ampoule with powder diluted in 1 ml of 0.9% saline solution in a single application at 4 points, in addition to a therapeutic exercise program in the teaching service to later do it at home that will be done daily for 4 months (cryotherapy for 15 minutes on the

plantar fascia, active mobilizations of the ankle and foot for 5 minutes, stretching exercises for the triceps surae and plantar fascia for 20 seconds, 3 repetitions, strengthening of intrinsic muscles of the foot).

Conceptual definition : Group B therapeutic program in which dexamethasone will be administered to patients with plantar fasciitis.

Operational definition: Program in which 2 ml of dexamethasone will be administered in an 8 mg/2 ml ampoule diluted in 2 ml of lidocaine injectable solution in a 50 ml bottle (20 mg/ml) in a single application at 1 point, in addition to a therapeutic exercise program in the teaching service to later do it at home that will be done daily for 4 months (cryotherapy for 15 minutes on the plantar fascia, active mobilizations of the ankle and foot for 5 minutes, stretching exercises for the triceps surae and plantar fascia for 20 seconds, 3 repetitions, strengthening of intrinsic muscles of the foot).

VII.III Period

The total period will consist of 8 months, of which 4 months will be for recruitment and 4 months for follow-up to evaluate its effectiveness in pain management, alignment, dorsiflexion range of motion, and foot and ankle functionality in plantar fasciitis.

VII.IV .I Selection criteria

INCLUSION CRITERIA:

1. Age over 18 years.
2. Any sex.
3. Diagnosis of plantar fasciitis (pain in the medial plantar calcaneal tubercle which gives rise to the site of plantar fascial insertion into the heel bone and/or pain along the path of its three bands) made by a physician specializing in Physical Medicine and Rehabilitation.

4. Voluntary acceptance of participation in the study.
5. Patients entitled to the Mexican Social Security Institute.

EXCLUSION CRITERIA:

1. Diagnosis of ankylosing spondylitis.
2. Pregnant women.
3. Previous infiltration treatment with any medication or substance applied to the plantar fascia or gastrocnemius muscles in the last six months.
4. Anticoagulant treatment.
5. History of local infection in the plantar fascia in the last three months.
6. Allergic to lidocaine, incobotulinum toxin or dexamethasone.
7. Patients not entitled to the Mexican Social Security Institute.
8. Patient's refusal to participate in the study.

ELIMINATION CRITERIA:

1.- Patients who abandon treatment.

VII.5 Methods

VII.VI Methodology

Participants in the study will be patients with a clinical diagnosis of plantar fasciitis who will be assessed using the EVA, AOFAS, FADI scales and measurement of the ankle dorsiflexion arch. The invitation to participate in the study will be extended, patients will be informed about the work to be performed and its purpose, and the application of Botulinum Toxin type A or Dexamethasone will subsequently be offered. By simple randomization, two study groups will be formed: GROUP A: Patients who accept intralesional infiltration with incobotulinum toxin 2 ampoules (200 IU) injectable solution presentation 100 IU ampoule with powder diluted in 1 ml of 0.9% saline solution in a single application in 4 points: insertion of the plantar fascia in the calcaneus (50 IU), site of greatest pain in the medial region of the plantar arch (50 IU), medial gastrocnemius (50 IU) and lateral gastrocnemius

(50 IU), at the end of the intervention a therapeutic exercise program will be provided in the service that will be carried out for 4 weeks. GROUP B: Patients who accept intralesional infiltration with 2 ml dexamethasone in an 8 mg/2 ml ampoule diluted in 2 ml of lidocaine injectable solution in a 50 ml bottle (20 mg/ml) in a single application in the anteromedial area of the calcaneus (area of greatest pain), at the end of the intervention a therapeutic exercise program will be provided in the service that will be carried out for 4 weeks.

In both cases, at the beginning of the intervention, an informed consent will be signed. At the end of the intervention, it will be recommended to avoid pressure or rubbing on the application sites, as well as not to take long walks for 48 hours , and in case of pain, apply a cold compress on the infiltration site for 10 minutes at home 3 times a day for 24 hours and subsequently, after 48 hours, a therapeutic exercise program will be provided in the teaching service to later do it at home, which will be done daily for 4 months (cryotherapy for 15 minutes on the plantar fascia, active mobilizations of the ankle and foot for 5 minutes, stretching exercises for the triceps surae and plantar fascia for 20 seconds, 3 repetitions, strengthening of intrinsic muscles of the foot).

Likewise, patients will be assessed in 4 visits: the first at the start of diagnostic detection, the second at 4 weeks post infiltration, the third at two months, the fourth at four months, with the EVA, AOFAS, FADI scales being assessed in all visits, which together will assess pain and functionality and disability of the foot and the measurement of dorsiflexion in 2 visits at the start of diagnostic detection and at 4 months.

VII.V.II Description of variables and units of measurement

DEPENDENT VARIABLES:

- Functional clinical status of ankle and foot (AOFAS scale)
- Functional disability index of the foot and ankle in activities of daily living (FADI SCALE)
- Functional Disability Index of the Foot and Ankle in Sport (FADI SCALE)
- Functionality (AOFAS Scale)

- Foot Alignment (AOFAS Scale)
- Pain (EVA, FADI and AOFAS).
- Ankle and foot disability
- Ankle dorsiflexion arch

INDEPENDENT VARIABLES:

- Age
- Gender
- Occupation
- Physical or sports activity
- BMI
- Foot to be treated

Variable		**Definitions**	**Variable type**	**Measurement level**	**Unit of measurement**
Dependent	**CLINICAL FUNCTIONAL STATUS OF THE ANKLE AND FOOT**	Conceptual: Term used to describe a patient's health status or condition. Operational: Result of the total summative score of the AOFAS scale	Qualitative	Nominal	Excellent=90-100 Good =80-89 Medium=70-79 Poor=<70
	INDEX OF FUNCTIONAL DISABILITY OF THE FOOT AND ANKLE IN ACTIVITIES OF DAILY LIVING	Conceptual: Index used to assess the result of the interaction between physical impairments and environmental barriers that limit full participation. Operational: Result of the total summative score of the FADI scale	Qualitative	Nominal	Absence of disability or pain = 100 Mild=80-99 Moderate=50-79 Severe:1-49 Maximum disability level = 0

	INDEX OF FUNCTIONAL DISABILITY OF THE FOOT AND ANKLE IN SPORTS ACTIVITIES	Conceptual: Index used to assess the result of the interaction between physical impairments and environmental barriers that limit full participation. Operational: Result of the total summative score of the FADI scale	Qualitative	Nominal	Absence of disability or pain = 100 Mild=80-99 Moderate=50-79 Severe:1-49 Maximum disability level = 0
	PAIN	Conceptual: unpleasant sensory and emotional experience associated with or similar to that associated with actual or potential tissue injury ” Operational: It will be evaluated using the FADI scale in the pain section, the AOFAS scale in the pain section and the Visual Analogue Pain Scale (VAS)	Qualitative	Ordinal	FADI 40=None 30= occasional 20=moderate 0=severe
			Qualitative	Ordinal	AOFAS 0=Unbearable 1=Severe pain 2=moderate pain 3= Mild pain 4=No pain
			Qualitative	Ordinal	EVE 0=absence of pain 1-4= Mild pain 5-7= Moderate pain 8-9= Severe non-disabling pain 10= Worst pain of your life, disabling pain
	FUNCTIONALITY	Conceptual: Ability of the subject to carry out daily life activities. Operational: It will be assessed with the AOFAS scale in the section on activity function, type of footwear, walking (maximum distance), types of terrain for walking, limping.	Qualitative	Ordinal	Activities 10= No limitation and no external support 7= No limitation in daily life, but yes in sports and without external support 4=Limitation in recreational life (crutch required) 0=Severe limitation even with crutch
			Qualitative	Ordinal	Type of footwear 5= Any footwear 3= Comfortable shoes only 0=Special footwear or orthoses
			Qualitative	Ordinal	Walking (maximum distance)

					10= More than 2km 7= Between 1.5 and 2 km 4= Between 0.5 and 1 km 0=less than 350 meters
			Qualitative	Ordinal	Type of terrain to walk on 10= No difficulty on any terrain 5= Some difficulty on uneven terrain and stairs 0=Difficulty on uneven terrain and stairs
			Qualitative	Ordinal	Limp 10=None 5=Obvious 0=Checked
	FUNCTIONALITY OF ACTIVITIES FOR DAILY LIVING	Conceptual: Set of features that make functions practical and useful for daily life Operational: It will be taken from the FADI scale in the functionality section in daily living activities	Qualitative	Ordinal	Stand up 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Walking on even terrain 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Walking on even terrain without shoes 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A

			Qualitative	Ordinal	Walking on uneven terrain 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Going up or down ramps 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Sleep FADI 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Taking the first steps after being at rest 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Walk for 15 min 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
					Walk for 10 min

			Qualitative	Ordinal	0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Walk for 5 minutes 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Take care of household activities 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Personal care activities 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Heavy work (pushing/pulling/climbing or carrying) 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Uphill walk 0= Unable to perform

					1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Downhill walk 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Climb stairs 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Go down stairs 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Perform activities of daily living 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Perform light/moderate work (standing, walking) 0= Unable to perform 1= Extreme difficulty

					2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Do recreational activities 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Climb on tiptoe 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Ordinal	Light to moderate work (standing or walking) 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty 3=Mild difficulty 4=No difficulty 5=N/A
	FOOT ALIENATION	Conceptual: Foot measurement used to determine the presence or absence of deviation towards the inside or outside of the foot. Operational: It will be taken from the AOFAS scale in the foot alignment section	Qualitative	Ordinal	0= Bad 8= Regular 15= Good
	PHYSICAL OR SPORTS ACTIVITY	Conceptual: Any bodily movement that requires energy expenditure. Planned, structured and repetitive activity aimed at improving or maintaining one or more	Qualitative	Ordinal	FADI 0= Unable to perform 1= Extreme difficulty 2=Moderate difficulty

		components of physical fitness. Operational: The ankle disability index (FADI) scale will be taken in the sports section and the clinical record to define the type of impact.			3=Mild difficulty 4=No difficulty 5=N/A
			Qualitative	Nominal	RECORD High Impact Low impact Does not perform
	MOBILITY ARC	Conceptual: Range of motion (degree of travel) or total angular/axial displacement allowed at a joint dosiflexion degrees at the time of data collection, will be expressed in the results by mobility range groups according to the American Academy of Orthopedic Surgeons AAOS.	Quantitative	Discreet	≤10°= Functional ≥20°=Complete
Independents	**AGE**	Conceptual: time that a person has lived from birth to a certain moment Operational: It will be taken from the clinical record.	Quantitative	Continue	1,2,3…
	AGE GROUP	Conceptual: a group of people who share an age or vital moment and who may be of statistical or academic interest. Operational: It will be taken from the clinical record.	Qualitative	Nominal	Youth=18 years old Adults = 19-64 years Senior adult => 65 years
	GENDER	Conceptual: It is the organic condition that distinguishes between masculine and feminine. Operational: It will be taken from the clinical record.	Qualitative	Nominal	Female Male
	OCCUPATION	Conceptual: Activity carried out by the person from which he obtains remuneration Operational: It will be taken from the clinical record.	Qualitative	Nominal	(TC) Loading work (TO) Office Work (H) Home (TP) Standing work

	BODY MASS INDEX (BMI)	Conceptual: index used to measure the relationship between weight and height, which allows identifying overweight and obesity in adults according to the Ministry of Health, resulting from the quotient of the formula (kilograms) ÷ (square meters). Operational: It will be taken from the clinical record.	Qualitative	Nominal	BMI<18.9= underweight BMI 18.50 - 24.9 = Normal BMI 25 - 29.9 = Overweight BMI 30 to 34.9 = Grade I obesity BMI 35 to 39.9 = Grade II obesity BMI>40=Grade III obesity
	FOOT TO BE TREATED	Conceptual: leg extremity, formed by a structure of bones, joints, muscles and other components. Operational: It will be taken from the clinical record.	Qualitative	Nominal	Right Left

PROCEDURE AND STATISTICAL ANALYSIS.

The information will be processed using Microsoft Excel version 2010 and SPSS version 11.5. A descriptive analysis will be performed using mean, median, average, standard deviation, percentages and proportions; and a comparative analysis using the Wilcoxon test .

In order to identify possible confounding variables , clinical and demographic characteristics will be compared. Student 's t test will be used to compare quantitative variables and CHi2 will be used to compare qualitative variables. If there is a difference in any of the variables, a multivariate model will be entered to adjust the effectiveness of the intervention. A value of $p < 0.05$ will be considered statistically significant. All analyses will be performed by intention to treat using the statistical program SPSS version 21.

PRESENTATION OF INFORMATION.

The information will be processed through the tools available in Microsoft Office® 2019 (Word, Excel, Power Point) as well as in the statistical/computer program IBM SPSS Software® version 21.

The information found and the findings will be presented through statements, tables and graphs as appropriate.

VII.V.III Human Resources

Primary care physicians and third-year resident physicians in the specialty of rehabilitation medicine qualified to perform intralesional procedures **.**

VII.V.IV Material resources

PROVIDED BY THE INSTITUTE:

- 2 Vials per patient of Incobotulinum Toxin , (Institutional KEY: 0100043620101)): (200 IU) presentation 100 IU ampoule in powder
- 1 vial of Dexamethasone (institutional KEY: 01000042410000): 2 ml ampoule presentation of 8 mg/2 ml
- 2ml of Lidocaine (Institutional CODE: 01000002620000): injectable solution, bottle with 50 ml (20mg/ml) to dilute dexamethasone.
- 1 ml of 0.9% saline solution (institutional CODE: 01000036080000): 0.9% injectable solution for every 100 ml, container with 250 ml to dilute with Botulinum toxin.
- 27g sterile needles
- Cotton swabs
- 70% ethyl alcohol
- 1 ml syringes
- 5 ml syringes
- White sheets
- Goniometer

VIII Ethical Considerations

The design of this study complies with the institutional, national and international standards that govern health research, as well as those that correspond to research on human beings. Including the Standard 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). As well as the Declaration of Helsinki.

According to the regulations of the General Health Law, Title Two “Ethical Aspects of Research in Human Beings”, Chapter I, this research protocol is considered to be research with greater than minimum risk, since random methods of assignment to therapeutic schemes will be used, for which a letter of informed consent will be requested. (Annex I)

The principles of bioethics are respected. It will be considered fair, since the results obtained in the present study will allow us to guide the management of patients with PF and guide it in order to obtain better functionality. 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 patients (beneficence).

The study is considered to be of minimal risk for participants, since the only procedure will be intralesional infiltration of Incobotulinum Toxin or Dexamethasone, with a physical therapy program and four assessment instruments, according to article 17, section II. The persons included will receive a clear and concrete explanation of the objective of the study in order to respect their dignity and well-being during the study; they will be informed of the freedom to withdraw from the study at any time when they no longer wish to participate without this affecting their personal interests.

Necessary measures will be taken to protect patient data through encryption, 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 on 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 .

IX Feasibility

This study has a high probability of completion due to the prevalence of plantar fasciitis in the Rehabilitation service of HGR 1.

Gant Schedule).

CLINICAL EFFECTS OF INTRALESIONAL APPLICATION OF INCOBOTULINUM TOXIN VS CORTICOSTEROID IN PATIENTS WITH PLANTAR FASCIITIS .

	Months 2024-2025								
	November-December	January-February	March-April	May-June	July-August	September	October	November	December
Gathering information.									
Preparation of the research protocol.									
Submission of the protocol for evaluation by the ethics and research committee.									
Data processing and analysis.									
Data interpretation									
Report preparation									
Communication of results									

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ANNEXES

Appendix 1 EVA PAIN RATING SCALE

Visual Analogue Scale

Instructions:
Please circle the number that best fits your level of pain, with 0 being no pain and 10 being the most pain.

Appendix 2 AMERICAN FOOT AND ANKLE SOCIETY SCALE (AOFAS)

Instructions: Please answer each question by circling the number that most accurately describes your current condition.

SECCIÓN 1. DOLOR

Ninguno	**40**
Ocasional	**30**
Moderado, diario	**20**
Severo, casi siempre presente	**0**

SECCIÓN 2. FUNCIÓN

1. Actividades

Sin limitación y sin soporte externo	**10**
Sin limitación en la vida diaria, pero sí en el deporte y sin soporte externo	**7**
Limitación en la vida recreativa (precisa muleta)	**4**
Limitación severa aún con muleta	**0**

2. Requerimiento de calzado

Cualquier calzado	**5**
Solo calzado confortable o uso de plantillas	**3**
Calzado especial u ortesis	**0**

3. Caminar (distancia máxima)

Más de 2 km	**10**
Entre 1,5 y 2 km	**7**
Entre 0,5 y 1 km	**4**
Menos de 350 m	**0**

4. Tipo de terreno para caminar

Sin dificultad en cualquier terreno	**10**
Alguna dificultad en terreno desigual y escaleras	**5**
Dificultad en terreno desigual y escaleras	**0**

5. Cojera

Ninguna	**10**
Evidente	**5**
Marcada	**0**

SECCIÓN 3. ALINEACIÓN DEL PIE

Buena, pie plantígrado bien alineado	**15**
Regular, pie plantígrado con algún Grado de desalineación pero asintomático	**8**
Mala, pie no plantígrado y sintomático	**0**

PUNTUACIÓN TOTAL MÁXIMO 100 PUNTOS

Appendix 3 THE FOOT AND ANKLE DISABILITY INDEX (FADI) SCALE

Instructions: Please answer each question according to the answer that best describes your condition within the past 7 days by marking the appropriate number in the box. If the activity in question is limited by something other than your ankle or foot, mark N/A (Not Applicable).

Score Activities of Daily Living FADI ____=sum of number of answers answered n (max = 26)/ n*4 X100

FADI Sport Score __= sum of number of answered questions n (max = 8)/ n*4 X100

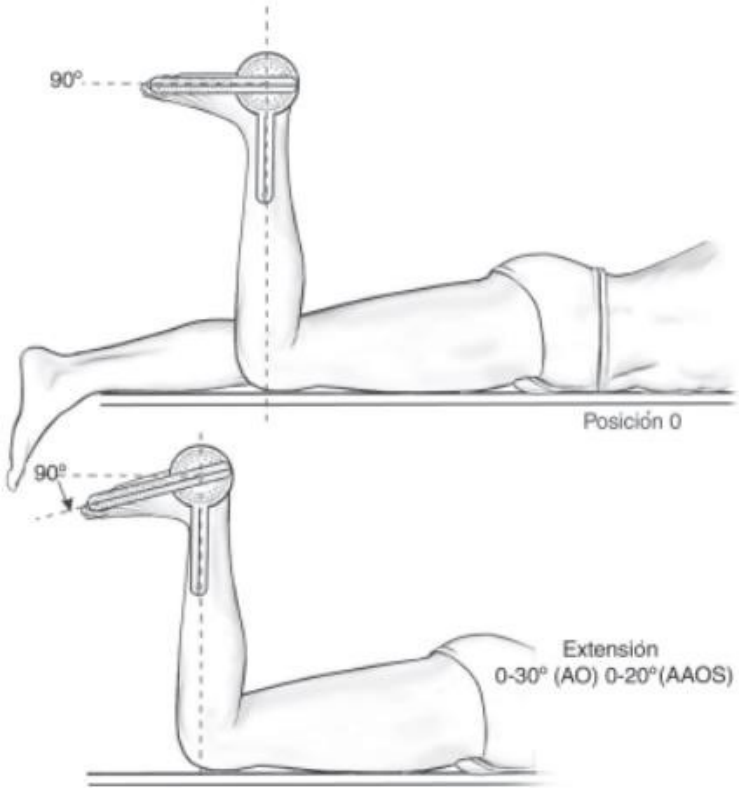
	Modulo actividades de la vida diaria					
Actividad	Sin dificultad 4	Dificultad extrema 3	Dificultad extrema 2	Dificultad extrema 1	Incapaz de realizar 0	No aplica (NA) X
1. Permanecer de pie						
2. Caminar en terreno regular						
3. Caminar en terreno regular sin calzado						
4. Caminar en terreno irregular						
5. Subir o bajar rampas						
6. Dormir						
7. Dar primeros pasos después de estar en reposo						
8. Caminar por 15 min						
9. Caminar por 10 min						
10. Caminar por 5 min						
11. Atender actividades del hogar						
12. Actividades del cuidado personal						
13. Trabajo pesado (empujar/jalar/escalar/ cargar)						
14. Caminata cuesta arriba						
15. Caminata cuesta abajo						
16. Subir escaleras						
17. Bajar escaleras						
18. Realizar actividades de la vida diaria						
19. Realizar trabajo leve/moderado (permanecer de pie, caminar)						
20. Realizar actividades recreativas						
21. Subir en puntillas						
22. Trabajo ligero a moderado (de pie o caminando)						

Módulo de dolor						
	Sin dolor 4	Dolor leve 3	Dolor moderado 2	Dolor severo 1	Incapaz de realizar 0	No aplica (NA) X
23. Nivel general del dolor						
24. Dolor durante actividades cotidianas						
25. Dolor en reposo						
26. Dolor al levantarse por la mañana						

Módulo de deportes.						
Actividad	Sin dificultad 4	Dificultad leve 3	Dificultad extrema 2	Dificultad extrema 1	Incapaz de realizar 0	No aplica (NA) X
1. Correr						
2. Caer de pie						
3. Realizar movimientos laterales						
4. Habilidad de realizar actividades con técnica normal						
5. Saltar						
6. Iniciar y parar rápidamente						
7. Actividades de bajo impacto						
8. Habilidad de participar en deporte de elección por el tiempo deseado						

Appendix 4 MEASUREMENT OF THE ANKLE DORSIFLEXION MOBILITY RANGE

Patient Name:	
ACTIVE MOBILITY RANGE OF ANKLE DORSIFLEXION	
VISIT 1 **(start of diagnostic detection)**	
VISIT 2 **(4 months post infiltration)**	



Annex 5 DATA COLLECTION INSTRUMENT

MEXICAN INSTITUTE OF SOCIAL SECURITY
YUCATAN DELEGATION
HEALTH EDUCATION AND RESEARCH COORDINATION
REGIONAL GENERAL HOSPITAL NO. 1 "LIC. IGNACIO GARCÍA TELLEZ"

DATA COLLECTION INSTRUMENT

TITLE: CLINICAL EFFECTS OF INTRALESIONAL APPLICATION OF INCOBOTULINUM TOXIN VS CORTICOSTEROID IN PATIENTS WITH PLANTAR FASCIITIS .

Sociodemographic
Name:
Social Security Number:
Age:
Sex:
Occupation:
Foot to be treated :
Sports activity:
Phones:

Physical examination.

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

Applications and evaluations

	DATE	EVE	AOOFAS	FADI	DORSIFLEXION
Start of diagnosis					
4 weeks					N/A
2 months					N/A
4 months					

Appendix 6 THERAPEUTIC EXERCISE PROGRAM

Therapeutic exercise program in the teaching service to later do it at home, which will be carried out daily for 4 months:

1. Cryotherapy for 15 minutes on the plantar fascia and active ankle and foot mobilization for 5 minutes (Fig 1)
2. Stretching exercises for the triceps surae (affected leg behind the other with the toes pointing towards the front heel, bend the front knee while the back knee is left stretched and with the heels fixed on the floor for 20 seconds) and plantar fascia for 20 seconds, 3 reps (Fig 2)
3. Strengthening intrinsic muscles of the foot (Fig 3)

FOLLOW-UP PERIOD	**PERFORM FROM MONDAY TO SUNDAY DAILY**
Start of diagnosis	
4 weeks	
2 months	
4 months	

FIG 1

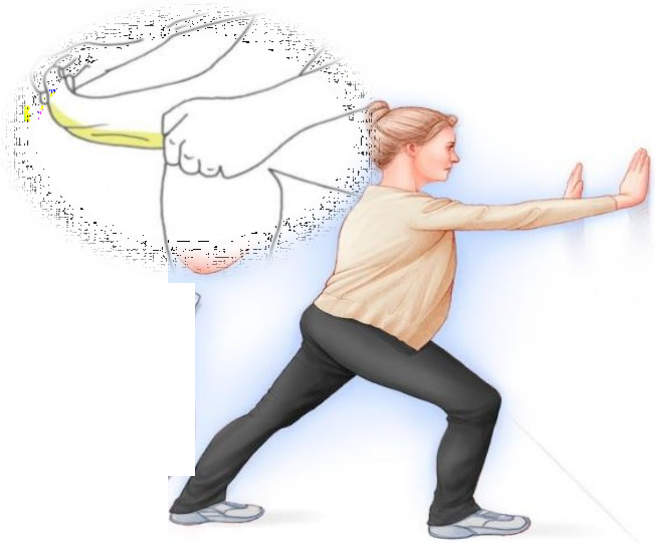


FIG 2

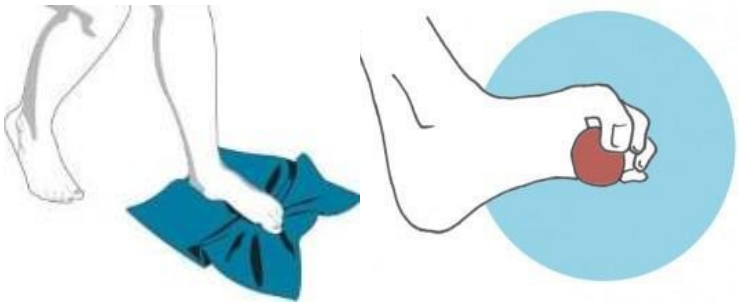


FIG 3

Annex ED CONSENT

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:	intralesional application of Incobotulinum Toxin vs. Corticosteroid in patients with plantar fasciitis.
Place and date:	HGR No.1, IMSS, Merida, Yucatan.2024.
Justification and objective of the study:	intralesional botulinum toxin A with the effect of intralesional corticosteroids in patients diagnosed with plantar fasciitis.
Procedures:	The group of patients referred to the physical medicine and rehabilitation service will be selected and will meet the selection criteria. They will receive their first consultation and will be invited to take part in the study. They will allow the use of data from their clinical records that are considered necessary for this study. They will answer questionnaires and participate in measurements upon admission and 4 weeks after entering the program.
Possible risks or discomforts	Pain at the application site, muscle pain typical of any rehabilitation program.
Possible benefits you will receive by participating in this study:	The application program of Incobotulinum Toxin or Dexamethasone offers the patient the possibility of reducing pain and stiffness as well as improving the functionality of the affected ankle and foot.
Information on results and treatment alternatives:	Incobotulinum Toxin or intralesional Dexamethasone will be announced .
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: - - -
Contributors: - - -

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