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CAMPUS DE EXCELENCIA INTERNACIONAL

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STUDY PROTOCOL AND STATISTICAL PLAN ANALYSIS

Carlos Vicente Vega

SALAMANCA, 2024

1. TITLE AND CONTACT RESEARCHER

PROJECT TITLE:"Effectiveness Of The Application Of Percutaneous Electrolysis On Muscular Scar Tissue"

MAIN RESEARCHER: Carlos Vicente Vega, Physiotherapist.

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2. SUMMARY

TITLE: Effectiveness of Percutaneous Electrolysis Application on Muscular Scar Tissue.

JUSTIFICATION: The significant advancements in invasive physiotherapy have led to the exploration of new treatment approaches for certain pathologies. In this case, percutaneous electrolysis appears to show promising results in the recovery of muscle injuries, which is why this line of research has been pursued in this study.

OBJECTIVE: To determine the effectiveness of an intervention involving the application of percutaneous electrolysis at different doses compared to a simulated intervention in adults with a muscle tear in the medial gastrocnemius.

MATERIALS AND METHODS: Approximately fifty adults with a muscle tear in the medial gastrocnemius will be included in this study. The first group will

APPLICABILITY OF EXPECTED RESULTS: The results of this study aim to provide valuable information regarding the effects of percutaneous electrolysis on muscle tears, improving the management of such injuries. Furthermore, this work seeks to contribute to the knowledge base on the use of percutaneous electrolysis by applying two different protocols with varying intensity and application time. This approach will provide insights into the treatment, management, and prognosis of muscle injuries addressed through invasive physiotherapy, specifically percutaneous electrolysis.

3. JUSTIFICATION

The completion of this research work is due to several reasons explained below.

We currently live in a society that, thanks to social and educational policies, increasingly places more importance on physical activity regardless of age. This situation leads to an increase in the incidence of sports-related injuries. There are many situations in which the muscular system of the body is put to use.

This makes it a tissue susceptible to injury. This type of pathology can have a good prognosis in individuals with a good repair capacity, however, in others it can cause problems, such as a higher risk of re-rupture, and long-term discomfort. (1)

The study of musculoskeletal injuries has been around for a long time, but it has not been until the last decade that there has been an exponential increase in research in this field. The physical preparation of athletes is increasingly more demanding, although muscle injury continues to be a problem at all levels, being one of the most prevalent pathologies in the world of sport. The bibliography regarding injury to this tissue proposes many action protocols, especially in acute stages, but more research is needed in more chronic stages.

Consulting this bibliography, we found some authors such as José Manuel Ibáñez, who, together with his collaborators, investigate the therapeutic potential of Percutaneous Electrolysis (PE) in musculoskeletal pathology, more specifically in chronic injuries. (2,3,4,5,6)

In most of their publications, they studied its effect on tendon pathologies, finding that percutaneous intratissue electrolysis in tendon tissue could have neutralizing effects on the injury, “cleaning” the area and promoting the arrival of repairing substances to it. Currently, there are several published articles that have studied the effects of this technique when a muscle-tendon injury occurs, both at the histological and functional level, obtaining both satisfactory results in terms of its early application. (2,3,4,5,6,7,8,9,10)

The question that we were asking ourselves at this time in relation to the data obtained from this bibliography is whether this same technique would be used in injuries that have not had an optimal recovery process and whose tissue does not have the initial characteristics, but more specifically, those of a fibrotic scar. In normal situations, the muscle-tendon tissue has innate regenerative capacities thanks to satellite cells after an injury (11,12,13,14). These cells, once the injury has occurred, are activated to regenerate the tissue, returning practically all the properties it had. On the contrary, these functions decrease with age.

aging, pathology or disease and spontaneous healing is not complete and the result is an area with a tissue quality very different from that before the injury resulting in a fibrotic scar (15).

The processes that occur in this incomplete recovery are several and to this day it has not been clearly clarified why and what are the mechanisms by which it occurs (12,16,17). That is why understanding the optimal management of these injuries is essential to restore the level of function prior to the injury, as well as to return values such as strength, joint range or risk of complications (**Mistake! Reference source not found.**,17).

For the reasons stated above, it has been decided to pursue this line of research by carrying out the project entitled**""EFFECTIVENESS OF THE APPLICATION OF PERCUTANEOUS INTRA-TISSUE ELECTROLYSIS IN MUSCULAR SCAR TISSUE"**

4. OBJECTIVES

RESEARCH QUESTION: In adults with medial gastrocnemius injury, how effective is percutaneous electrolysis in terms of pain, kinesiophobia, fatigue and mobility?

HYPOTHESIS: The working hypothesis of the present study is the following: "The application of percutaneous electrolysis (PE) at high intensity (3 mA) and at low intensity (0.3 mA) will be more effective in the treatment of muscle tears of the internal calf than the simulated application of percutaneous electrolysis in adult subjects."

GENERAL OBJECTIVE: To determine the effectiveness of an intervention consisting of the application of percutaneous electrolysis in different doses versus the application of a simulated intervention in adults who present a muscle tear in the internal calf.

SPECIFIC OBJECTIVES:

1. To analyze the effectiveness of Percutaneous Intratisular Electrolysis, in its different forms. intensities, applied to the internal gastrocnemius muscle, in terms of myofascial pain in patients participating in the study, both at rest and during muscle contraction, measured using the visual analog scale (VAS).
2. To analyze the effectiveness of a simulated intervention applied to the internal gastrocnemius muscle, in terms of myofascial pain in patients participating in the study, both at rest and during muscle contraction, measured through the visual analog scale (VAS).
3. Evaluate and compare the effect of the protocols on the level of kinesiophobia of the participating subjects through the TSK-11SV questionnaire.
4. To demonstrate whether there are differences in muscle fatigue of the affected muscles of the participants in both groups.
5. To objectively determine the degree of range of ankle dorsiflexion mobility with full knee extension of the patients participating in the study.

5. MATERIAL AND METHODS

A) TYPE OF STUDY

This doctoral thesis consists of a study which is defined as a randomized, experimental and controlled clinical trial, with three parallel groups, prospective, longitudinal and with a blind evaluation for the researcher.

B) MATERIALS AND/OR TECHNIQUES USED

Regarding the materials / physical resources necessary to carry out this study, they are stated below.

- Room at the Miguel Naranjo Center for the first consultation and different evaluations.
- Office with a stretcher and the equipment required for a physiotherapy consultation.
- Certified medical device (EPI Alpha, Barcelona, Spain)
- Needles for the application of the EP technique.
- Ultrasound

As for the techniques used, different ones will be used for each study group and are developed below.

1.Working methodology of the High Intensity Percutaneous Electrolysis group.

A sterile, disposable stainless steel needle of different lengths depending on the area to be treated will be connected to the EP device. The gauge of these needles will be 0.25 mm. A current of 3 mA will be applied 3 times for a duration of 3 seconds each. To avoid bias, the technique will be performed for 90 seconds, just like the low-intensity treatment group, and in the last 20 seconds the current will be applied with the parameters described above. Three sessions will be applied divided into 3 consecutive weeks. This parameter has been previously used in recent studies (10,20).

2.Working methodology of the low intensity percutaneous electrolysis group

This technique will be performed with the same instrument as the high intensity technique. It differs from the previous treatment group in that the current intensity in this case will be 0.3 mA for 90 seconds. Similarly, 3 sessions will be applied divided into 21 consecutive days (21,22).

3.Simulated Percutaneous Electrolysis working methodology.

The needle and the EP device will be connected in the same way as for the other treatment groups. The needle will be inserted without reaching the lesion area and the characteristic sound of turning on the EP machine will be made. It will last 90 seconds and at no time will the galvanic current be applied. The same aseptic precautions will be applied, in addition to the same final hemostasis guidelines and the same post-treatment guidelines provided to all the other subjects in the study.

C) STUDY POPULATION

The study population for this clinical trial will be completed by a sample of approximately 50 adults between the ages of 18 and 65 who have suffered a muscle injury in the medial gastrocnemius. The researchers will consider a tear in the medial gastrocnemius if this pathology had any of the following characteristics:

- Medical diagnosis of fibrillar tear in the inner calf.
- Physiotherapeutic diagnosis of muscle tear after ultrasound examination.
- Pain in the GM area that coincides with a previously diagnosed fibrillar tear.

The**inclusion criteria**for the following study will be the following:

- Age over 18 years and under 65 years.
- Muscle tear in the medial gastrocnemius.
- With pain in the area of the injury.

- That you have been informed of the purpose, as well as the risks and benefits of this study and that you have provided your written consent to participate in the trial.

- Available for tracking.

The**exclusion criteria**are listed below:

- Active rehabilitation in other musculoskeletal pathology.
- Belenophobia
- Immunosuppression.
- Uncontrolled metabolic diseases.

D) STUDY VARIABLES:

1. Sociodemographic variables

1. Age (years).
2. Sex.
3. Weight (kg).
4. Height (m).
5. Tear size (cm)
6. Location, Since the medial gastrocnemius is a peripheral myoconnective region, we will distinguish between tendon, myotendinous, muscular and myofascial injuries (23).
7. Chronicity: This section sets out the time since the rupture occurred. It is considered to be part of the 2nd week if it occurred before 14 days, 3rd week if it occurred before 21 days, 4th week if less than 28 days have passed, and between 4 and 8th week if less than 56 days have passed.

2. Outcome variables.

1. EVA pain scale.

The evaluation of the pain of the participants both in an upright position (without contraction) and in contraction will be carried out through a Verbal Scale

Pain score of 10 points (0 = no pain, 10 = maximum tolerable pain). Subjects will be asked to numerically rate the pain in a neutral standing position and in a position with both heels raised, also commonly known as standing on their toes. In the latter position, a score of 10 will be given if the subjects are unable to maintain this position for at least one full lift.

2. Kinesiophobia questionnaire (TSK-11SV).

Recovery from painful injuries is associated with fear of movement, also known as kinesiophobia (24). It could be defined as an irrational or excessive fear of movement due to fear of injury or re-injury. For this reason, a kinesiophobia questionnaire (annex II) will be provided at the beginning of the study (day I, evaluation and first intervention) to all participants to assess kinesiophobia of performing certain movements that may cause pain or worsen previous injuries. It consists of 11 questions with a minimum score of 11 and a maximum of 44.

3. Ankle dorsiflexion range with the knee straight.

The evaluation of this variable will be carried out by measuring the angle obtained from the dorsiflexion of the ankle with a knee extension. This stretch is commonly performed in sports practice, so patients are generally already familiar with it..Stretching will be done with participants barefoot.. Likewise, participants will be instructed on how to place the test..The leg to be tested was positioned so that the foot was placed on the midline of an area marked on the floor, and the foot of the healthy leg was placed forward at a distance of one step. The end point of the gastrocnemius stretch was defined as the point at which participants felt discomfort without lifting the heel and without pelvic rotation. Patients would place their hands against the wall for balance and would be asked to maintain the extended position of the hip and knee joints during the stretch (25).

During the stretch, participants will be instructed to reach a pain or discomfort level of 7 or greater on a scale of 0 to 10 and therefore to hold the stretch at approximately this perceived intensity.

A digital camera (Canon EOS 2000D 24.1 MP) will be placed on the ground at a distance of 2 meters perpendicular to the plane of movement of the right leg to record the standing ankle dorsiflexion angle. The ankle joint angle in stretching will be analyzed by reflective markers placed on the knee (fibular head), ankle (external malleolus) and fifth metatarsal (head) and calculated by free software (RULER- Ergonauts Software. Polytechnic University of Valencia). The maximum standing dorsiflexion is defined as the intersection of a line joining the knee and ankle markers and the horizontal line crossing the heel and fifth metatarsal. (25)

4. Muscle fatigue of the triceps surae.

The assessment of fatigue in this muscle group will be carried out by performing a heel-raise test (4) at the beginning and at the end of the test for all participants who have completed it. The test consists of placing the patient on one leg and with the help of a metronome at a speed of 40 beats per minute (Garmin Fénix 5/5S), he is asked to raise his heel (4). When the patient is unable to raise his heel for 3 consecutive beats, fatigue will be considered. Light support on a wall is authorized to save the patient's balance.

E) WORK PLAN.

The study will be carried out as follows;

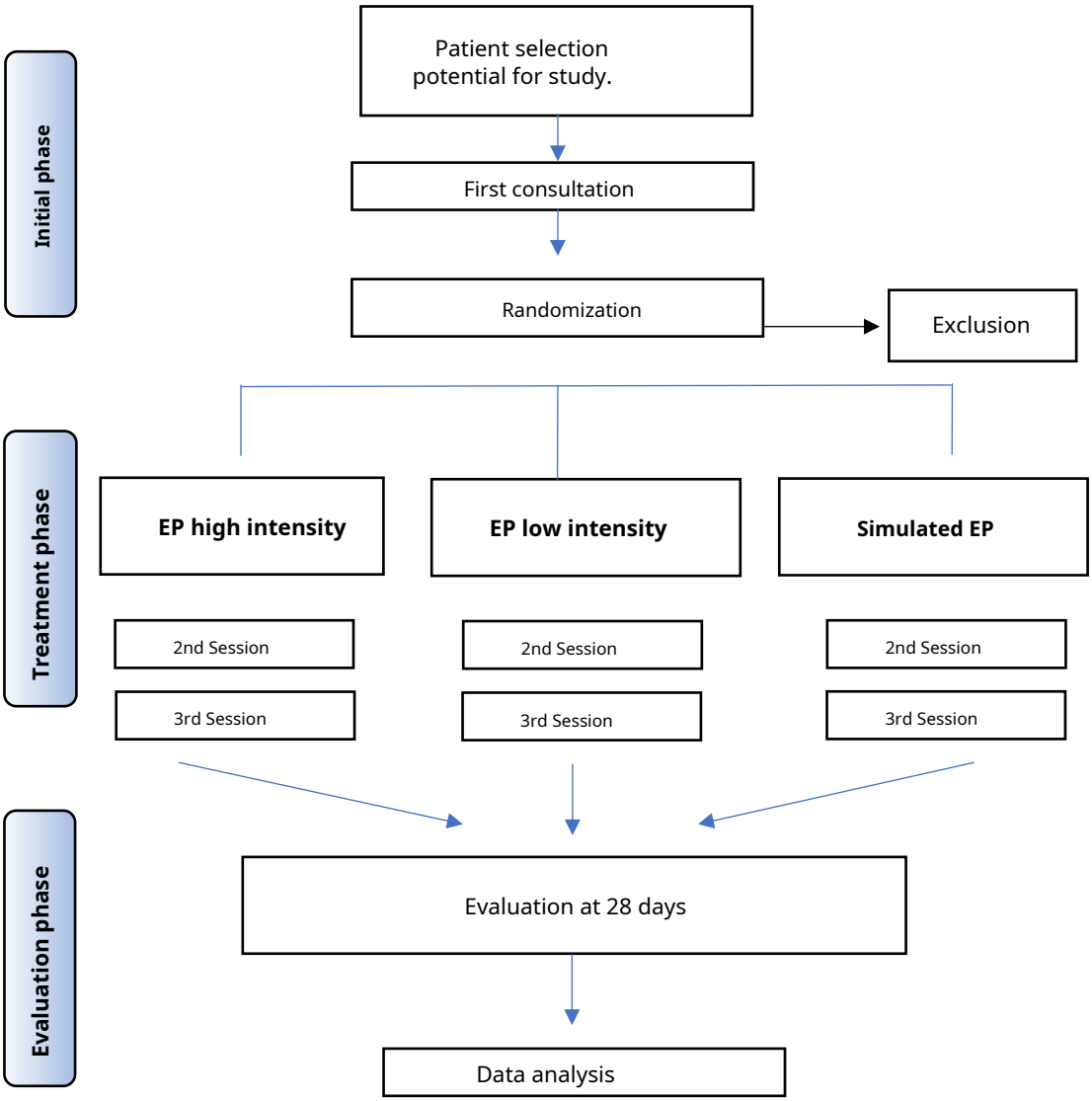
- *Phase I or initial*: Pre-study consultations will begin. Any patient who calls the centre to express their wish to take part in the study or who comes to the centre naturally will be given an appointment for a consultation with the principal investigator. All patients who strictly meet the eligibility criteria will be offered to participate in the study.

- *Phase II or treatment*: The entire treatment will be applied by the same physiotherapist (principal investigator) according to the randomization table that will be made so that each patient is assigned a treatment; high intensity EP, low intensity EP or sham EP. The treatment will be carried out in three sessions divided into three

weeks (days 1, 7 and 14) The person in charge of collecting the data will not be aware of which treatment each patient receives and will collect the data before the interventions.

- *Phase III or evaluation:*Patients will be scheduled for appointments two weeks after the last visit (day 28). The data from this last visit will be collected by the same person as the previous ones. All tests will be performed to collect the data and they will be given a telephone number in case they have any adverse events.

Study timeline.



F) ANALYSIS PLAN

For the coding and analysis of the data, the SPSS 22.0 statistical program will be used. For the treatment of quantitative variables, tables of absolute and relative frequencies will be prepared; in the case of quantitative variables, frequency measures will be used to determine their distribution, also obtaining their mean and standard deviation. The Kolmogorov-Smimov test will be performed to check the normality of the distribution. For the comparison of means of the continuous dependent variables, a bivariate statistical analysis will be performed using the Student T test. In the case of ordinal dependent variables, a comparison of medians will be performed using the bivariate analysis applying the Mann-Whitney test. In all cases, a 95% confidence interval and a precision error of 5% will be established.

G) LIMITATIONS AND POSSIBLE BIASES OF THE STUDY

This study has a number of limitations that should be taken into account when designing future research.

Firstly, the sample of participants will include people aged between 18 and 82, which may lead to biases due to the different variables that can influence different ages. It should also be noted that all people who participate will do so voluntarily by calling the centre to ask about the study or by showing up at the centre, so the possibility of bias due to voluntary participation must be taken into account.

It should also be noted that only one follow-up consultation will be carried out two weeks after the last intervention, so we will not have information on the behaviour of the variables beyond that date and therefore we will not be able to analyse the long-term results. It would be interesting to add post-intervention evaluations, as well as to study possible long-term recurrences.

6 DATA COLLECTION SHEETS

DATA COLLECTION SHEET

SOCIODEMOGRAPHIC VARIABLES

Identifier:	Birthdate:
Sex:	Height (m):
Weight (kg):	Chronicity of the injury (weeks):
Location of the lesion:	Tear size (cm):

MYOFASCIAL PAIN VAS SCALE 1-10.

	PRE-INTERVENTION	POST-INTERVENTION
PAIN AT REST		
PAIN IN LOAD		

KINESIOPHOBIA LEVEL

	PRE-INTERVENTION	POST-INTERVENTION
AVERAGE SCORE		

ANKLE DORSIFLEXION RANGE WITH KNEE IN FULL EXTENSION

	PRE-INTERVENTION	POST-INTERVENTION
ANGLE		

MUSCLE FATIGUE OF THE TRICEPS SURAE

	PRE-INTERVENTION	POST-INTERVENTION
TEST SCORE		

8. BIBLIOGRAPHY

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2. Valera, J., Muñoz, F., & Sanchez, J. (2010). *Effectiveness of percutaneous intratissue electrolysis (EPI®) in chronic insertional patellar tendinopathy*. Trauma MAPFRE Foundation, 21(4), 227-36.
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play" time in professional soccer players: A case series. Revista Fisioterapia Invasiva/Journal of Invasive Techniques in Physical Therapy, 3(01), 038-044.

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9. ETHICAL CONSIDERATIONS

Participation in this study will be voluntary, anonymous, unpaid. and, in any case, after signing an informed consent form that will be given at the beginning of the treatment. This consent form details all the relevant aspects of this study. No data of the participants can be related to any particular individual, because the results of the study, as well as the data of the participants, will be published in a format that guarantees their absolute confidentiality. All patients will have the opportunity to ask questions. 100% of the participants will be aware of the voluntary nature of the study, as well as that they can leave it at any time without penalty or commitment. This study protocol will be sent for approval by the Salamanca Biomedical Research Institute (IBSAL). The research will proceed according to the Declaration of Helsinki on medical research on human beings, all data will be treated in accordance with the precepts of Organic Law 3/2018 of December 5 on the protection of personal data and guarantees of digital rights.

10. CURICULUM VITAE OF THE RESEARCHERS

Fecha del CVA	29/09/2023

Parte A. DATOS PERSONALES

Nombre	Carlos		
Apellidos	Vicente Vega		
Sexo	Hombre	Fecha de Nacimiento	16/11/1997
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A.2. Situación profesional anterior (incluye interrupciones en la carrera investigadora - indicar meses totales, según texto convocatoria-)

Periodo	Puesto / Institución / País
2021 - 2023	Fisioterapeuta / Centro Miguel Naranjo
2020 - 2021	Fisioterapeuta / CROSECON SA
2021 - 2021	Fisioterapeuta / Clínica CEMTRO

A.3. Formación académica

Grado/Master/Tesis	Universidad / País	Año
Máster en fisioterapia deportiva	Universidad Pontificia de Salamanca / España	2021
Graduado o Graduada en Fisioterapia	Universidad de Salamanca / España	2020

Parte B. RESUMEN DEL CV

Graduado en Fisioterapia por la Universidad de Salamanca especializado en fisioterapia deportiva por la Universidad Pontificia de Salamanca. Actualmente me encuentro terminando mi tesis doctoral en la Universidad de Salamanca. Mi experiencia laboral como fisioterapeuta comenzó en varios clubes deportivos como el Salamanca Fútbol Sala y el Getafe Fútbol Club y continuó en centros privados de fisioterapia como son Crosecon, Clínica CEMTRO y Centro Miguel Naranjo. Mi pasión por la investigación y la enseñanza vienen desde que comencé el grado universitario.

B.1. Breve descripción del Trabajo de Fin de Grado (TFG) y puntuación obtenida

El trabajo de fin de grado fué una revisión bibliográfica sobre los tratamientos de fisioterapia en la discopatia degenerativa. El ejercicio físico fue el tratamiento más respaldado por la comunidad científica. La nota obtenida fue un 9 sobre 10.

B.2. Breve descripción del Trabajo de Fin de Máster (TFM) y puntuación obtenida

El trabajo de Fin de Máster fue una propuesta de estudio, que más tarde pude seguir con mi tesis doctoral, sobre el efecto de la prevención de lesiones en el triceps sural a través del entrenamiento de la propiocepción. La nota obtenida fue de un 8 sobre 10.

Parte C. LISTADO DE APORTACIONES MÁS RELEVANTES

C.1. Publicaciones más importantes en libros y revistas con "peer review" y conferencias

AC: Autor de correspondencia; (nº x / nº y): posición firma solicitante / total autores. Si aplica, indique el número de citaciones

Revisión bibliográfica. Vicente Vega, C.; Blanco Blanco, J F.2020. Systematic review of current evidence regarding physiotherapy treatment in cervical degenerative disc. Repositorio documental de la Universidad de Salamanca.

Fecha del CVA	19/09/2023

Parte A. DATOS PERSONALES

Nombre	Sergio		
Apellidos	Varela Rodríguez		
Sexo	Hombre	Fecha de Nacimiento	05/02/1996
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Open Researcher and Contributor ID (ORCID)	0000-0001-6269-3883		

A.1. Situación profesional actual

Puesto	Fisioterapeuta		
Fecha inicio	2019		
Organismo / Institución	Clínica FisioStudio Salamanca		
Departamento / Centro			
País	España	Teléfono	
Palabras clave			

A.2. Situación profesional anterior (incluye interrupciones en la carrera investigadora - indicar meses totales, según texto convocatoria-)

Periodo	Puesto / Institución / País
2019 - 2020	Fisioterapeuta / Mutua Montañesa
2018 - 2019	Fisioterapeuta / Mutua Montañesa
2018 - 2018	Fisioterapeuta / Clínica Fisiorivher
2018 - 2018	Fisioterapeuta / Mutua Montañesa

A.3. Formación académica

Grado/Master/Tesis	Universidad / País	Año
Salud, discapacidad, dependencia y bienestar	Universidad de Salamanca	2022
Máster en Terapia Manual Ortopédica en el Tratamiento del Dolor	Universidad Europea de Madrid	2019
Grado en Fisioterapia	Universidad de Salamanca	2018

Parte C. LISTADO DE APORTACIONES MÁS RELEVANTES

C.1. Publicaciones más importantes en libros y revistas con "peer review" y conferencias

AC: Autor de correspondencia; (nº x / nº y): posición firma solicitante / total autores. Si aplica, indique el número de citaciones

1 **Artículo científico**. Sánchez-González, Juan Luis; Navarro-López, Víctor; Cañada-Sánchez; Juárez-Vela, Raúl; Ruiz de Viñaspre-Hernández, Regina; Varela-Rodríguez. 2023. Efficacy of different intensities of percutaneous electrolysis for musculoskeletal pain: A systematic review and meta-analysis. Frontiers in Medicine. Frontiers. 10-1101447.

2 **Artículo científico**. Varela-Rodríguez, Sergio; Sánchez-Sánchez; Velasco, Enrique; Delicado-Miralles, Miguel; Sánchez González, Juan Luis. 2022. Endogenous Pain Modulation in Response to a Single Session of Percutaneous Electrolysis in Healthy Population: A Double-Blinded Randomized Clinical Trial. Journal of Clinical Medicine. MDPI. 11, pp.2289.

3 **Artículo científico**. Varela-Rodríguez S.; Sánchez-González J.L.; Sánchez-Sánchez J.L.; Delicado-Miralles M.; Velasco E.; Fernández-de-las-Peñas; Calderón-Díez L.2021. Effects of Percutaneous Electrolysis on Endogenous Pain Modulation: A Randomized Controlled Trial Study Protocol.Brain Sciences. MDPI. 11-6, pp.801.

4 **Artículo científico**. Varela-Rodríguez S.; Cáceres-Pajuelo J.E.; Sánchez-Sánchez J.L.2021. Percutaneous Electrolysis in Patients with Muskuloskeletal Disorders: A Systematic Review.Journal of Molecular and Genetic Medicine. Hilaris. 15-2, pp.476.

C.2. Congresos

Pie y tobillo: otra gran pandemia. II Congreso Internacional de Fisioterapia Invasiva y Musculoesquelética. Fisiocampus y Universidad Francisco de Vitoria. 2021.

C.3. Proyectos o líneas de investigación

1 **Proyecto**. Influencia de la electrólisis percutánea en la modulación endógena del dolor. Colegio Profesional de Fisioterapeutas de Castilla y León. 2021-2022. 1.763,96 €.

11. ANNEXES

TSK-11SV QUESTIONNAIRE

Tampa Scale for Kinesiophobia(Spanish adaptation. Gómez-Perez, López-Martinez and (Ruiz-Párraga, 2011)

INSTRUCTIONS: A series of statements are listed in which you have to determine to what extent this occurs according to the following scale:

1	2	3	4
Completely disagree			Completely OK

1.	**I am afraid of getting injured if I exercise**	**1 2 3 4**
2.	**If I let myself be overcome by pain, the pain would increase**	**1 2 3 4**
3.	**My body is telling me that I have something serious.**	**1 2 3 4**
4.	**Having pain always means that there is an injury in the body**	**1 2 3 4**
5.	**I'm afraid of accidentally injuring myself.**	**1 2 3 4**
6.	**The safest way to prevent further pain is to be careful and not make unnecessary movements.**	**1 2 3 4**
7.	**Pain tells me when I should stop the activity to avoid injury.**	**1 2 3 4**
8.	**It wouldn't hurt so much if I didn't have something serious going on in my body.**	**1 2 3 4**
9.	**It is not safe for a person with my condition to do physical activity.**	**1 2 3 4**
10.	**I can't do everything that normal people do because I could easily get injured.**	**1 2 3 4**
11.	**No one should do physical activities when they are in pain.**	**1 2 3 4**