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Comparing a new treatment for shoulder tendon injuries with traditional rehab methods

Submission date
08/03/2025

Recruitment status
No longer recruiting

Registration date
25/03/2025

Overall study status
Completed

Last Edited
20/06/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to compare a new treatment method called percutaneous electrolysis (PNE) with traditional rehabilitation methods for treating shoulder tendon injuries. Traditional treatments like medication, physiotherapy, and invasive procedures are not always effective and can have side effects. The study will evaluate how well PNE improves muscle strength, pain, range of motion, and other factors in patients with shoulder tendon injuries.

Who can participate?
Adults aged 35 to 55 years with shoulder tendon injuries (specifically supraspinatus tendon tendinopathy) that have lasted between 3 months and 2 years can participate. Both men and women are eligible.

What does the study involve?
Participants will be divided into three groups of 30. Each group will undergo different treatments:
The first group will receive PNE treatment and perform specific exercises.
The second group will receive traditional rehabilitation treatments like TENS, high-energy laser therapy, TECAR therapy, and exercises.
The third group will perform exercises recommended for tendon injuries.
Participants will have their shoulder range of motion measured and undergo clinical tests and muscle assessments before and during the study.

What are the possible benefits and risks of participating?
Participants may benefit from improved shoulder function and reduced pain. However, there may be risks associated with the treatments, such as discomfort from the procedures or exercises.

Where is the study run from?
Health Center "Salus" (Poland)
Medical Center Provita (Poland)

When is the study starting and how long is it expected to run for?

Who is funding the study?
Medical Center Provita (Poland)

Who is the main contact?
Robert Trybulski, rtrybulski.provita@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Ethics Committee of the Polish Physiotherapy Society No. 24/2022 of December 8, 2022

Study information

Scientific Title
Comparison of the treatment effects of nonreactive tendinopathy of the supraspinatus tendon: treatment with percutaneous tendon electrolysis, which is responsible for the conservative and control rule

Acronym

PNE

Study objectives
The purpose of this study is to compare different treatment protocols for supraspinatus tendinopathy. In addition, the study results will provide information on at what week of treatment patients can expect to see improvement in function or possible pain reduction during specific treatment protocols. In addition, data collected from the myotonometer will provide information on whether/how specific properties of the supraspinatus muscle change during a specific treatment period in different treatment protocols. We hypothesized that the PNE therapy protocol would demonstrate superior efficacy in reducing pain, improving mobility, and reducing biomechanical properties of tendons in rotator cuff tendinopathy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/12/2022, Ethics Committee of the Polish Physiotherapy Society (al. Jerozolimskie 93, Warsaw, 02-001, Poland; +48 22 230 23 80; Komisjietykibadan@kif.info.pl), ref: ref.: no. 9 /2022

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice, Other therapist office

Study type(s)
Prevention, Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Treatment of rotator cuff tendinopathy

Interventions
The research group meeting the criteria will be divided into three groups of 30 participants. Each participant will have their range of motion in the glenohumeral joint measured with an inclinometer before the start of the study. In addition, each participant will undergo the following clinical tests: "Jobe's" Test, "Full Can" Test, "Whipple" Test. Then, each participant will be examined with a myotonometer on the belly of the supraspinatus muscle to determine 5 parameters (tone, stiffness, elasticity, relaxation, creep). The first research group will be treated with percutaneous electrolysis (EPTE) and a set of exercises with progressively increasing resistance. The second group will be treated for 6 weeks (twice a week) with conservative rehabilitation consisting of TENS current, 7W high-energy laser, TECAR therapy and a set of exercises with progressively increasing resistance. The third group of 30 patients will be the

control group, which will perform exercises indicated in the treatment of tendinopathy, every other day, for 6 weeks. At the beginning of the new week of treatment, each of the subjects will have the following measurements performed: range of motion in the glenohumeral joint using an inclinometer, clinical tests (Jobe, Full Can, Whipple) and measurements will be performed with a myotonometer.

Intervention Type
Other

Primary outcome measure
Assessed at baseline and 6 weeks of treatment:
1. Muscle tension (F = Hz), stiffness (S = N/m), flexibility and relaxation (ms) were measured using a myotonometer (MyotonPRO AS, Myoton Ltd, Estonia 2021)
2. Muscle pain threshold (PT-kG or N) was measured using a FDIX algesimeter (Wagner Instruments, Greenwich, CT, USA 2013)
3. Muscle strength (W) was measured using a handheld dynamometer (EH106 China 2020)
4. Range of Motion was measured using a K-Force Move v3 – electronic goniometer (Italy 2021)
All measurements taken between 10 a.m. and 12 p.m. Measurements are performed on the following muscles: deltoid, supraspinatus, infraspinatus, levator scapulae, equinocostal, sternocleidomastoid, subscapularis, teres minor major, biceps brachii and triceps brachii

Secondary outcome measures
Assessed at baseline and 6 weeks of treatment:
1. Tendon thickness and bundle length [mm] measured with SONOMED DOPPLER MD4 (China 2020) with a 3-15 MHz transducer
2. Clinical tests (Jobe Test, Full Can Test, Whipple Test)
3. NES numerical pain scale [0-10]

Overall study start date
20/02/2022

Completion date
16/06/2025

Eligibility

Key inclusion criteria
1. Patients with clinical symptoms of supraspinatus tendon tendinopathy, visible and confirmed tendinopathy of this tendon in an imaging study (USG and/or MRI)
2. Duration of symptoms between 3 months and 2 years
3. Women and men
4. Age: 35 to 55 years

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit

35 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
Coexisting tendinopathies of other rotator cuff tendons, subacromial-subdeltoid bursitis, secondary tendinopathy after supraspinatus tendon reconstruction or report a mechanical injury in the interview, calcification tendinopathy of the supraspinatus tendon (tendon calcification). The study will include patients regardless of the extent of tendinopathic changes in the tendon and the location of these changes in the tendon.

Date of first enrolment
10/12/2024

Date of final enrolment
02/02/2025

Locations

Countries of recruitment
Poland

Study participating centre
Health Center "Salus"
ul. Zielona 8
Słupsk
Poland
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Study participating centre
Medical Center Provita
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Sponsor information

Organisation
Salus

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Sponsor type
Industry

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Provita Medical Center

Results and Publications

Publication and dissemination plan
All studies will be published in indexed scientific journals

Intention to publish date
15/09/2025

Individual participant data (IPD) sharing plan
Data sets collected during the study will be made available upon request and will be stored on the server of the Provita Medical Center - the research coordinator. The person responsible for storage and sharing is the project manager, Dr. Robert Tryblski, e-mail: rtrybulski.provita@gmail.com. The consent form attached to the application was signed by each participant, indicating their consent to share their data. The study was conducted in accordance with the Declaration of Helsinki with the approval of the ethics committee (consent attached to the application).

IPD sharing plan summary
Available on request