

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

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		<input type="checkbox"/> Results
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		<input checked="" type="checkbox"/> 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?

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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

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

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; Komisjetykibadan@kif.info.pl), ref: ref.: no. 9 /2022

### **Study design**

Interventional randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Prevention, Treatment

### **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(s)**

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 algometer (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

### **Key secondary outcome(s)**

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]

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

35 years

### **Upper age limit**

55 years

### **Sex**

All

### **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

76-200

**Study participating centre**

**Medical Center Provita**

Al. United Europe 7

Żory

Poland

44-240

## **Sponsor information**

**Organisation**

Salus

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

## Results and Publications

### **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 Trybalski, 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