# Extracorporeal shock wave therapy for the treatment of chronic non-calcific tendinopathy of the supraspinatus

Submission date Recruitment status Prospectively registered 07/11/2010 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 20/12/2010 Completed [X] Results [ ] Individual participant data Last Edited Condition category 05/11/2012 Musculoskeletal Diseases

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Prof Olimpio Galasso

#### Contact details

Viale Europa Catanzaro Italy 88100

#### Additional identifiers

Protocol serial number N/A

# Study information

#### Scientific Title

Extracorporeal shock wave therapy for the treatment of chronic non-calcific tendinopathy of the supraspinatus: a double-blind, randomised, placebo-controlled trial

#### Study objectives

To investigate the efficacy and safety of low energy shock waves as compared to placebo in the treatment of uncalcifying tendinopathy of the rotator cuff.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Local Ethics Committee (Comitato Etico Azienda Ospedaliera Universitaria Integrata) approved

#### Study design

Double-blind randomised placebo-controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Non-calcifying tendinopathy of supraspinatus tendon

#### **Interventions**

The treatment regimen requires administration of two treatment sessions with 3000 impulses separated by 7 days. The sham treatment will entail use of the Modulith SLK in which the shockwave generator has been disconnected although all other aspects of the device will appear to be normal, including the audible sound characteristic of the generator.

All patients will be required to have two follow-up visits to complete the study. The initial follow-up visit will occur 6 weeks after the last treatment. The final follow-up visit will occur 3 months after the final treatment.

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome(s)

- 1. Efficacy: Constant-Murley Score (CMS), measured at baseline, 6 weeks and three months follow up
- 2. Safety (adverse effects), measured immediately after treatment, at the beginning of the second session of shock waves and at 6 weeks and three months follow up

#### Key secondary outcome(s))

Roentgenographic and magnetic resonance images (MRI) changes, measured at baseline and three months follow up

#### Completion date

05/05/2003

## **Eligibility**

#### Key inclusion criteria

- 1. Male and non-pregnant female patients 18 years of age or older (women of child-bearing potential must have a negative serum pregnancy test performed within 1 14 days prior to the treatment procedure) suffering from chronic non-calcific supraspinatus tendinopathy as diagnosed by X-ray, magnetic resonance imaging (MRI) and physical examination
- 2. Patient has not responded to a standard course of non-pharmacological and non-surgical conservative treatment for a minimum of 4 months. Non-surgical conservative treatment may consist of: therapeutic exercise, ultrasound, iontophoresis, cryotherapy, and immobilisation or activity modification.
- 3. Patient has not responded to non-surgical, pharmacological conservative treatment and has had at least one sub-acromial steroid injection and at least one course of the standard dose of prescribed non-steroidal anti-inflammatory drugs (NSAIDs) or other pharmacological therapy a minimum of thirty days prior to SV
- 4. Diagnosis of supraspinatus tendinopathy is only in one shoulder
- 5. Patient has free passive range of movement and at least 90 degrees active abduction in the affected shoulder
- 6. Patient is willing to participate in the study and return for all scheduled follow-up visits
- 7. Patient is capable of giving, and has given, written informed consent

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. Patient has a history of uncontrolled severe hypertension (systolic pressure greater than 180 mmHg, diastolic pressure greater than 110 mmHg)
- 2. Patient has unstable or uncontrolled angina, uncontrolled heart failure, or serious uncontrolled ventricular arrhythmias
- 3. Patient has a white blood cell count less than 2,000 or greater than 15,000, and/or platelet count less than 50,000
- 4. Patient has a known bleeding disorder or is currently being treated with anticoagulant therapy
- 5. Patient is currently being treated with a narcotic or NSAIDs and/or has used analgesics or NSAIDs within the 72 hours prior to the SV
- 6. Patient has participated in any other shoulder pain treatment research study within 30 days prior to the SV
- 7. Patient has had prior shoulder surgery
- 8. Patient is complaining of pain in both shoulders
- 9. Patient has malignant tumours, irrespective of location
- 10. Patient has a cardiac pacemaker implant
- 11. Patient has anatomy that prevents the focusing of the device into the shoulder in the area of

the supraspinatus tendon (e.g., extensive scarring, misalignment of side fractures, non-unions or delayed fracture healing, congenital malformation, etc.)

- 12. Patient has any upper extremity neurological disorder as diagnosed from focused neurological exam (e.g. thoracic outlet syndrome, reflex sympathetic dystrophy, etc.)
- 13. Patient has a full-thickness rotator cuff tear of any of four tendons as seen on MRI
- 14. Patient has an acromiohumeral interval less than 7 mm as measured on a standard AP X-ray or severe symptomatic degenerative changes in the glenohumeral or acromioclavicular joint
- 15. Patient has acute subacromial bursitis as diagnosed by physical examination findings and MRI
- 16. Patient has generalised polyarthritis, rheumatoid arthritis
- 17. Patient is allergic to local anaesthetic

# Date of first enrolment 07/10/2002

Date of final enrolment 05/05/2003

#### Locations

# Countries of recruitment Italy

Study participating centre Viale Europa Catanzaro Italy 88100

## Sponsor information

#### Organisation

Storz Medical AG (Switzerland)

#### **ROR**

https://ror.org/049vzz986

# Funder(s)

#### Funder type

University/education

#### **Funder Name**

#### Funder Name

University Magna Graecia, Catanzaro (Italy) - School of Medicine University

## **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	results	06/06/2012	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes