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

Submission date 07/11/2010	**Recruitment status** No longer recruiting
Registration date 20/12/2010	**Overall study status** Completed
Last Edited 05/11/2012	**Condition category** Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

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

Overall study start date
07/10/2002

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

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)

Sponsor details
Lohstampfestrasse 8
Tägerwilen
Switzerland
8274

Sponsor type
Industry

Website
http://www.storzmedical.com/

ROR
https://ror.org/049vzz986

Funder(s)

Funder type
University/education

Funder Name
Storz Medical AG, Tägerwilen (Switzerland)

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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