

Ultrasound therapy for medial epicondylitis. A double blind randomised placebo controlled trial.

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 31/10/2019	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

N0544093511

Study information

Scientific Title

Ultrasound therapy for medial epicondylitis. A double blind randomised placebo controlled trial.

Study objectives

Ultrasound therapy for medial epicondylitis

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Musculoskeletal Diseases: Medial epicondylitis

Interventions

To evaluate the effects of ultrasound in the treatment of medial epicondylitis. Adult subjects with medial epicondylitis will be randomised to receive either ultrasound (US) or sham (S) therapy. In the US group pulsed ultrasound will be delivered at a standardised dosage, initially five times weekly for 3 weeks, then three times weekly for 3 weeks. A single machine will be used and calibrated twice daily. The patient, assessor and treating clinician will all be blinded. Outcome measures will be recorded at 6 weeks and at 9 months from baseline. These will include a forearm evaluation score and pain (primary measures), grip strength, flexibility, inflammation (thermographic score), quality of life and general health status a summary item of status of the injury and a follow up transition item.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

11/09/2003

Eligibility**Key inclusion criteria**

200 Adults aged 18-75 (PROJ).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Lower age limit

18 years

Upper age limit

75 years

Sex

Not Specified

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

11/09/2000

Date of final enrolment

11/09/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Box No 204

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Other

Funder Name

Cambridge Consortium - Addenbrooke's (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration