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

Submission date
12/09/2003

Registration date
12/09/2003

Last Edited
31/10/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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
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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
11/09/2000

Completion date
11/09/2003

Eligibility

Key inclusion criteria
200 Adults aged 18-75 (PROJ).

Participant type(s)
Patient

Age group
Not Specified

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Not Specified

Target number of participants
200

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
England

United Kingdom

Study participating centre
Box No 204
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Other

Funder Name
Cambridge Consortium - Addenbrooke's (UK)

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