ISRCTN34475330 https://doi.org/10.1186/ISRCTN34475330

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

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/12/2013	Musculoskeletal Diseases	

Plain English Summary
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
N0544103837

Study information

Scientific Title

Study hypothesis
Ultrasound therapy for lateral 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

Condition
Lateral epicondylitis (tennis elbow)

Interventions
To evaluate the effects of ultrasound in the treatment of lateral epicondylitis. Adult subjects with lateral 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 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

Overall study end date
11/09/2003

Eligibility

Participant inclusion criteria
200 18-75 year olds (PROJ)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
200

Participant exclusion criteria
Does not match inclusion criteria

Recruitment start date
11/09/2000

Recruitment end date
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2006		Yes	No