

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Cathy Speed

### Contact details

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United Kingdom  
CB2 2QQ

## 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