

# A randomised placebo-controlled trial of local steroid injection and nonsteroidal anti-inflammatory tablets for the treatment of tennis elbow

<b>Submission date</b> 03/01/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/01/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/08/2007	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

H0526

## **Study information**

**Scientific Title**

**Study objectives**

To compare the clinical effectiveness of local corticosteroid injections, standard non-steroidal anti-inflammatory drugs and simple analgesics for the treatment of lateral epicondylitis in primary care.

**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)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

**Health condition(s) or problem(s) studied**

Tennis elbow

**Interventions**

1. Methyl prednisolone (20 mg) and lignocaine by local injection
2. Naproxen 500 mg bd for 2 weeks versus placebo tablets

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

local corticosteroid injections, standard non-steroidal anti-inflammatory drugs and simple analgesics

**Primary outcome measure**

Participants' global assessment of improvement (5-point scale) at 4 weeks.

**Secondary outcome measures**

1. Pain severity
2. Impairment of function
3. Severity of main complaint
4. Disability
5. Grip strength
6. Local tenderness
7. Co-interventions
8. Time off paid employment

**Overall study start date**

01/11/1995

**Completion date**

31/12/1998

## **Eligibility**

**Key inclusion criteria**

Consecutive patients aged 18-70 years who consulted their GP with a new episode of lateral epicondylitis (pain and tenderness in the lateral region of the elbow and no consultation with symptoms in the same elbow in the preceding 12 months) during November 1995 to December 1997.

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

70 Years

**Sex**

Not Specified

**Target number of participants**

164

**Key exclusion criteria**

1. History of inflammatory arthritis or gross structural abnormality of the elbow
2. Contraindications to non-steroidal anti-inflammatories or local steroid injection
3. Pregnancy or breast feeding

**Date of first enrolment**

01/11/1995

**Date of final enrolment**

31/12/1998

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre****Department of Rheumatology**

Stoke-on-Trent

United Kingdom

ST6 7AG

## Sponsor information

**Organisation**

Arthritis Research Campaign (ARC) (UK)

**Sponsor details**

Copeman House

St Mary's Court

St Mary's Gate

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Derbyshire

United Kingdom

S41 7TD

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info@arc.org.uk

**Sponsor type**

Charity

**Website**

<http://www.arc.org.uk>

ROR

<https://ror.org/02jkpm469>

## Funder(s)

### Funder type

Charity

### Funder Name

Arthritis Research Campaign

## 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?
<a href="#">Results article</a>	Results	09/10/1999		Yes	No
<a href="#">Abstract results</a>		01/03/2002		No	No
<a href="#">Abstract results</a>		01/04/2002		No	No