ISRCTN34466933 https://doi.org/10.1186/ISRCTN34466933

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

Submission date
03/01/2003

Recruitment status
No longer recruiting

Registration date
03/01/2003

Overall study status
Completed

Last Edited
03/08/2007

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr EM Hay

Contact details
Department of Rheumatology
Haywood Hospital
High Lane
Burslem
Stoke-on-Trent
United Kingdom
ST6 7AG
+44 (0)1782 715444
e.m.hay@cphc.keele.ac.uk

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
Chesterfield
Derbyshire
United Kingdom
S41 7TD
-
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?
Results article	Results	09/10/1999		Yes	No
Abstract results		01/03/2002		No	No
Abstract results		01/04/2002		No	No