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The long term effectiveness of steroid injection for shoulder pain; a pragmatic randomised comparison with physiotherapy in primary care

Submission date
03/01/2003

Recruitment status
No longer recruiting

Registration date
03/01/2003

Overall study status
Completed

Last Edited
11/07/2007

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
H0563

Study information

Scientific Title

Study objectives
To compare the long term effectiveness of local steroid injections administered by general practitioners with practice based physiotherapy for treating patients presenting in primary care with new episodes of unilateral shoulder pain.

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Shoulder pain

Interventions
1. Methyl prednisolone (40 mg) and lignocaine by local injection
2. Physiotherapy

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Methyl prednisolone

Primary outcome measure
The primary outcome was disability at 6 months measured using a shoulder disability Questionnaire.

Secondary outcome measures
Secondary outcomes included: participants global assessment of change compared with baseline; rating of pain severity; impairment of function; severity of main complaint; ranges of movement; co-interventions.

Overall study start date
01/06/1998

Completion date
30/09/2000

Eligibility

Key inclusion criteria
1. Males and females over 18 years with a clinical diagnosis of unilateral shoulder pain
2. First consultation with GP for this episode
3. Ability to understand and give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
207

Key exclusion criteria
A history of inflammatory arthritis, polymyalgia rheumatica, or gross structural or neurological abnormality of the shoulder; contraindications to local steroid injection; history or examination leading to a suspicion of potentially serious disease; referred pain from neck or internal organs; clinical findings of ruptured rotator cuff; previous fracture or surgery to shoulder, upper limb, neck, or thorax; previous physical therapy for shoulder pain within the past 12 months; pregnancy or breast feeding.

Date of first enrolment
01/06/1998

Date of final enrolment
30/09/2000

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
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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?
Results article	Results	01/05/2003		Yes	No
Results article	Results	01/02/2004		Yes	No