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

Submission date	Recruitment status	Prospectively registered		
03/01/2003	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
03/01/2003	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
11/07/2007	Musculoskeletal Diseases			

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

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