

The Shoulder Window of Opportunity Study

Submission date 07/03/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/05/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/05/2013	Condition category Injury, Occupational Diseases, Poisoning	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0705/789

Study information

Scientific Title

Acronym

SWOPS

Study objectives

To investigate whether a combined approach of physiotherapy with subacromial corticosteroid injection is more effective in reducing pain and disability at 12 weeks than physiotherapy alone in older patients with moderate to severe shoulder pain due to subacromial impingement syndrome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Leeds (West) Research Ethics Committee on 31/10/05, project reference 05/Q1205/174

Study design

Two-arm 12-week randomised trial with observational follow-up to 24 weeks

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

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

Subacromial impingement syndrome

Interventions

Participants are randomised to receive one of the following treatments:

1. Subacromial corticosteroid (triamcinolone acetonide) injection combined with a standardised physiotherapy regimen
2. Standardised physiotherapy regimen alone

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Corticosteroid

Primary outcome measure

The shoulder pain and disability index (SPADI) at week 12 will be considered the primary outcome

Secondary outcome measures

1. Participant global assessment of change from baseline will be recorded using a five-point scale
2. Overall health status will be recorded using the Euroqol
3. Information on use of therapeutic interventions from weeks 12 to 24 will be recorded

Overall study start date

14/03/2006

Completion date

14/03/2009

Eligibility**Key inclusion criteria**

1. Age 40 years or older with unilateral shoulder pain. Shoulder pain is defined as pain in the shoulder region, including the upper arm, elicited or exacerbated by active or passive shoulder movement.
2. Subject rating of pain as moderate or severe on a 3-point scale (mild/moderate/severe)
3. Non-capsular pattern of restriction where capsular pattern is defined as painful and limited passive glenohumeral mobility, lateral rotation must be relatively more restricted than abduction and medial rotation. Some loss of lateral rotation permitted but no more than 25% compared to opposite side.
4. Positive impingement test (Hawkins or Neer)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

220

Key exclusion criteria

1. Unable to give informed consent
2. Known blood coagulation disorders
3. Evidence of referred pain from the cervical spine or internal organs

4. Neurological abnormality of the shoulder
5. History of rheumatoid arthritis, polymyalgia rheumatica or other inflammatory arthritis
6. Bilateral shoulder pain
7. Contraindications to local steroid/lidocaine injection
8. Pregnancy or breastfeeding
9. Previous fracture, dislocation or surgery to shoulder, upper limb, neck, or thorax
10. No previous steroid injections in the symptomatic shoulder in the previous 6 months
11. No previous physiotherapy for the symptomatic shoulder in the previous 6 months

Date of first enrolment

14/03/2006

Date of final enrolment

14/03/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Leeds General Infirmary**

Leeds

United Kingdom

LS1 3EX

Sponsor information

Organisation

West Yorkshire Primary Care Research and Development Unit (UK)

Sponsor details

Bradford South and West Primary Care Trust

Allerton Health Centre

Bell Dean Road

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Sponsor type

Government

Funder(s)

Funder type

Charity

Funder Name

Arthritis UK (UK) - formerly Arthritis Research Campaign (ref: 17236)

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	28/06/2010		Yes	No
Results article	results	01/08/2013		Yes	No