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The Shoulder Window of Opportunity Study

Submission date
07/03/2006

Registration date
11/05/2006

Last Edited
08/05/2013

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Injury, Occupational Diseases, Poisoning

[_] 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

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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.br/>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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Leeds General Infirmary
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
West Yorkshire Primary Care Research and Development Unit (UK)

Funder(s)

Funder type
Charity

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

Results and Publications

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