ISRCTN42399123 https://doi.org/10.1186/ISRCTN42399123

Subacromial impingement syndrome and pain

Submission date
22/03/2011

Recruitment status
No longer recruiting

Registration date
22/03/2011

Overall study status
Completed

Last Edited
08/01/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Subacromial impingement syndrome (SIS) is a condition that involves pain and weakness in the shoulder muscle. It is the most common cause of shoulder problems, affecting 1 in 3 adults. It is usually treated with a combination of exercises and medications including corticosteroids (which reduce inflammation (swelling)). Exercises meant to treat the SIS are usually standard for everyone and not customised for each patient and it would be interesting to see whether personalised exercises work better, and whether using ultrasound (a scan that uses soundwaves to create an image of the inside of the body on a screen) can improve the accuracy of corticosteroid injections. There is a lack of evidence on the impact of exercise and corticosteroid injection for treating SIS. The aim of this study is to find out if corticosteroid injections in combination with individualised exercise are the most effective treatment for SIS.

Who can participate?
Adults with a diagnosis of SIS

What does the study involve?
Participants are randomly allocated to one of four treatment groups. Group one participants take part in an individualised exercise program run by a physiotherapist and receive corticosteroid injections guided by ultrasound. This involves using an ultrasound probe to show the area in question so that the injection can be given accurately. Group two participants receive an information sheet with advice about exercises and receive an injection guided by an ultrasound. Group three participants take part in an individualised exercise program run by a physiotherapist and have an injection which is not guided by ultrasound. Group four participants receive an information sheet with advice about exercises and their injection is unguided. Participants complete a number of questionnaires in order to assess their shoulder pain at the start of the study, 6 weeks, 6 months and 12 months after treatment.

What are the possible benefits and risks of participating?
Participants may experience pain relief or improvement to their shoulder symptoms. There are very few risks with steroid injections and participants will be given information on how to manage risks. Due to the exercise treatment, there is risk of temporary soreness in the shoulder.

Where is the study run from?
Primary Care Sciences Research Centre (lead centre) and two musculoskeletal Clinical Assessment and Treatment Services in Staffordshire (UK)

When is the study starting and how long is it expected to run for?
March 2011 to March 2014

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Nadine Foster
n.foster@keele.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Nadine Foster

Contact details
Primary Care Sciences Research Centre, Keele
Newcastle
United Kingdom
ST5 5BG
-
n.foster@keele.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9731

Study information

Scientific Title
Subacromial impingement syndrome and pain: a randomised controlled trial of exercise and injection (the SUPPORT trial)

Acronym
SUPPORT

Study objectives
The SUPPORT trial is a factorial (2x2) trial, that will investigate the clinical and cost-effectiveness of exercise and injection for subacromial impingement syndrome (SIS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
10/H1202/72; First MREC approval date 15/10/2010

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Musculoskeletal; Subtopic: Not Assigned, Musculoskeletal (all Subtopics); Disease: Musculoskeletal, All Diseases

Interventions
Patients who provide written informed consent for trial participation will be randomised to one of four treatment groups, namely:
1. Ultrasound-guided corticosteroid injection, with physiotherapist-led individualised, supervised and progressed exercise
2. Ultrasound-guided corticosteroid injection, with an advice and exercise leaflet
3. Unguided (blind) corticosteroid injection, with physiotherapist-led individualised, supervised and progressed exercise
4. Unguided (blind) corticosteroid injection, with an advice and exercise leaflet.

The trial is organised and sponsored by the Arthritis Research UK Primary Care Centre, at Keele University, and is funded by the National Institute for Health Research: Research for Patient Benefit Programme. We plan to recruit 252 patients from within North and South Staffordshire to this trial.

Ultrasound-guided subacromial, Interface clinicians within the musculoskeletal interface service shoulder clinics will deliver ultrasound (US)-guided subacromial injection using a standard technique. Ultrasound examinations will be performed using the LOGIQe system with a 12MHz transducer.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The Shoulder Pain and Disability Index (SPADI); Timepoint(s): Baseline questionnaire, 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months

Secondary outcome measures
1. 11-item Tampa scale of kinesophobia; Timepoint(s): Baseline questionnaire, 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months
2. Brief Illness Perception Questionnaire (5-items); Timepoint(s): Baseline questionnaire, 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months
3. Confidence in treatment; Timepoint(s): 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months follow-up questionnaire
4. Consultation in primary and secondary care; Timepoint(s): 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months follow-up questionnaire
5. Current employment status; Timepoint(s): : Baseline questionnaire, 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months 6. Effect of shoulder disability on typical everyday activities; Timepoint(s): Baseline questionnaire, 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months
7. EURO-QOL (EQ5D); Timepoint(s): Baseline questionnaire, 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months
8. Exercise adherence; Timepoint(s): 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months follow-up questionnaire
9. Global Change; Timepoint(s): 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months follow-up questionnaire
10. Hospital Admission; Timepoint(s): 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months follow-up questionnaire
11. Medical investigations; Timepoint(s): 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months follow-up questionnaire 12. Medication use (prescribed and over-the-counter); Timepoint(s): 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months follow-up questionnaire
13. MOS-Short Form 12 (SF-12); Timepoint(s): Baseline questionnaire, 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months
14. Pain manikin; Timepoint(s): Baseline questionnaire, 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months
15. Pain self-efficacy questionnaire; Timepoint(s): Baseline questionnaire, 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 mon
16. Potential Adverse Events; Timepoint(s): 6 weeks follow-up questionnaire, case report form from physiotherapists, General Practitioner (GP) 17. Receipt of benefits, if not working; Timepoint(s): Baseline questionnaire, 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months
17.Repeat injections; Timepoint(s): 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months follow-up questionnaire
18. Shoulder pain at night; Timepoint(s): Baseline questionnaire, 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months 19.Shoulder Pain Severity; Timepoint(s): Baseline questionnaire, 1 week follow-up telephone contact, 6 weeks follow-up

questionnaire, 6 month; 20. Stanford presenteeism scale (SPS-6); Timepoint(s): Baseline questionnaire, 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months
20. Treatment satisfaction; Timepoint(s): 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months follow-up questionnaire
21. Work absence; Timepoint(s): Baseline questionnaire, 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months
22. Work performance; Timepoint(s): Baseline questionnaire, 6 weeks follow-up questionnaire, 6 months follow-up questionnaire and 12 months

Overall study start date
01/03/2011

Completion date
31/03/2014

Eligibility

Key inclusion criteria
1. 18 years and over, referred to interface service shoulder clinics with shoulder problems
2. No history of significant shoulder trauma, for example, fracture or full thickness cuff tear
3. A clinical diagnosis of subacromial impingement syndrome (SIS) i.e. pain in deltoid insertion area, positive Neer and HawkinsKennedy tests, pain on shoulder abduction
Accurate diagnosis of SIS is challenging, but a combination of the patients history and response to Neer and HawkinsKennedy tests (to rule SIS out with a negative test) and pain on shoulder abduction (to rule SIS in with a positive test) provides optimal sensitivity and specificity. Patients will not be required to undergo diagnostic imaging (eg MRI) to reflect current practice where treatment choices are informed by clinical findings;
Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 252; UK Sample Size: 252

Total final enrolment
256

Key exclusion criteria

·1. Below 18 years old
2. Those whose main complaint is due to neck problems, acromioclavicular pathology, or other primary shoulder disorders including adhesive capsulitis or full thickness cuff tear
3. Potentially serious pathology (inflammatory arthritis, polymyalgia rheumatica, malignancy etc) or ipsilateral shoulder surgery/replacement
4. Those already on a surgical waiting list for shoulder surgery
5. Contraindications to local corticosteroid injection (known blood coagulation disorders, warfarin therapy)
6. Participation in a shoulderfocused exercise programme or shoulder injection in the last month
7. Inability to provide written informed consent, complete written questionnaires, or read instruction leaflets written in English

Date of first enrolment
08/06/2011

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Care Sciences Research Centre, Keele
Newcastle
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University (UK)

Sponsor details
Keele
Newcastle
England
United Kingdom
ST5 5BG

Sponsor type
University/education

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Central commissioning facility (CCF)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/12/2017

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?
Protocol article	protocol	14/03/2014		Yes	No
Other publications	development and delivery	01/12/2017		Yes	No
Results article	results	01/03/2021	24/08/2020	Yes	No
Results article	cost-effectiveness results	07/01/2021	08/01/2021	Yes	No