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SPiRIT. Shoulder pain: randomised trial of injectable treatments

Submission date	Recruitment status	[X] Prospectively registered
15/09/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/09/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/07/2024	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Shoulder pain accounts for 1–2% of all adult consultations with a GP in the UK. Despite being a common injury, shoulder pain does not always have a favourable outcome with current treatments.
Currently, the most common treatments are steroid injections combined with physiotherapy or keyhole surgery but there are questions about whether using steroid injections is actually safe in the long term.
This has led to the development of new injectable treatments aimed to help tendons repair themselves. These are termed 'biologic' injections.
The aim of this study is to see if it is feasible to compare one of these biologic-injection treatments against steroid injections.

Who can participate?
All adults, 18 years and older who have symptoms suggestive of subacromial pain syndrome and would normally be offered CorticoSteroid injections treatment for their injury.

What does the study involve?
50 participants will be recruited to the trial. Half will receive CorticoSteroid injection treatment and half will receive a 'biologic' injection. All participants will be asked for a sample of blood. This blood will be spun to create the Autologous Protein Solution for the ‘biologic’ injection treatment. Those participants receiving CorticoSteroid injections will have their blood samples discarded, this is to ensure that participants will not know which injection they have received.

What are the possible benefits and risks of participating?
Both treatments are used across the NHS so there is no specific advantage to taking part in the study, however, participation will help us improve treatment for future patients with similar pain. After receiving either injection, some participants may experience mild to moderate pain local to the injection site. The rare risk of infection following an injection for both treatments is the same.

Where is the study run from?
The University of Oxford is the lead centre for the study, and the day-to-day running of the study is being completed by Oxford Trauma and Emergency Care.

When is the study starting and how long is it expected to run for?
August 2021 to June 2023

Who is funding the study?
National Institute for Health Research (NIHR) – Research for Patient Benefit (RfPB) (UK).

Who is the main contact?
Kylea Draper, spirit@ndorms.ox.ac.uk
Prof. Steve Gwilym, steve.gwilym@ndorms.ox.ac.uk

Study website
https://www.ndorms.ox.ac.uk/clinical-trials/current-trials-and-studies/spirit

Contact information

Type(s)
Scientific

Contact name
Prof Steve Gwilym

Contact details
Oxford Trauma & Emergency Care (OTEC)
Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS)
Kadoorie Centre
Level 3, John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU
+44 (0)7554669554
steve.gwilym@ndorms.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
294982

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50349, NIHR201473, IRAS 294982

Study information

Scientific Title
SPiRIT (Shoulder Pain: Randomised trial of Injectable Treatments) A randomised feasibility study of autologous protein solution (APS) vs corticosteroids for treating subacromial shoulder pain.

Acronym
SPIRIT

Study objectives
The aim of the SPIRIT is to see if it is feasible to compare a autologous protein solution against corticosteroids for treating subacronmial shoulder pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/09/2021, Cambridge Central REC (City Link Nottingham, Equinox House, Nottingham, NG2 4LA, UK; +44 (0)2071048384; cambridgecentral.rec@hra.nhs.uk), ref: 21/EE /0211

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

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

Interventions
The informed consent process will commence when the usual-care clinician decides the patient is to be referred for therapeutic injection and meets the eligibility criteria for the SPIRIT trial. The clinical team will initially approach the patient about the trial. As per normal standard practice, the patient will be contacted to arrange a date, time and location of their treatment appointment. In this phone call the study team will introduce the trial to the potential participant. If the patient indicates interest in participating they will be booked into a specific SPiRIT intervention clinic and will have a participant information sheet (PIS) sent via email At the

'SPIRIT clinic' appointment a trial clinician will have an informed consent discussion with patient and if happy to proceed the patient will provide written electronic consent using a trial tablet or computer. Once completed, an electronic version of the signed consent form will be automatically emailed to the participant.
All Baseline CRFs will then be completed on web-based data collection service.
Once informed consent has been given and Baseline CRFs completed, the participant will be randomised by the local research team using a web-based service. Allocations will be implemented immediately after randomisation, participants will be blinded to the injection that they receive.
To avoid bias in the delivery of the intervention and completion of patient reported outcomes, the patients are to be kept blind about the treatment that is allocated. This blinding will be achieved by collecting the blood sample required for APS (55 ml, approximately the volume of an egg cup) from both groups of patients. In the intervention group, this blood will be used for the preparation of the APS; in the control group, this blood will be sham-prepared as APS, but discarded. This approach was discussed with the Oxford Trauma PPI group and they collectively agreed that this was an acceptable approach to avoid any placebo-effect. Researchers and clinical team are not blinded to the intervention received.
Participants will then receive a weekly text/email/phone call up to week 8 post-randomisation with a link to a visual analogue scale asking them to indicate their level of pain in the previous 24 hours.
At 3 and 6 months post-randomisation, participants will be contacted via text/email/phone call and invited to complete the VAS, PROMIS, OSS, EQ-5D-5L, WPAI, resource use and complications questionnaires.
If patients do not complete the triggered URL Link they will be contacted by phone by the central trial team within 7 days.

Drugs and dosage:
Intervention: Autologous Protein Solution (APS). Approximately 55ml of blood will be taken from the participant and will be spun on a centrifuge. This will result in approx. 5mls of APS solution which will be injected into the site of the shoulder pain. This treatment will occur once during the trial, immediately post randomisation.
Comparator: Corticosteroids (CSI). Approximately 55ml of blood will be taken from the participant and will be discarded. This is to ensure blinding. The participant will then receive injection containing Depo-medrone (40mg) mixed with 3mls of 0.5% bupivacaine local anaesthetic. This treatment will occur once during the trial, immediately post randomisation.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Depo-medrone, bupivacaine

Primary outcome measure
1. The conversion rate of eligible to randomised participants until the end of the recruitment period measured using screening logs
2. Total number of participants recruited until the end of the recruitment period measured using screening logs

Secondary outcome measures
1. Levels of retention at follow-up dates until the end of follow-up period (will be measured using all patient facing case report forms)
2. Data compliance at follow-up until the end of follow-up period (will be measured using all patient facing case report forms)
3. Completion rates of PROMIS upper limb physical function, PROMIS pain interference questionnaire, Oxford Shoulder Score (OSS), EQ-5D-5L score at baseline, 3 months and 6 months post-randomisation (will be measured using the following questionnaires :PROMIS upper limb physical function, PROMIS pain interference questionnaire, Oxford Shoulder Score (OSS), EQ-5D-5L)
4. Completion rates of Pain visual analogue score (VAS) at baseline, weekly up to 8 weeks, 3 and 6 months post-randomisation (will be measured using the following questionnaires. Pain Visual Analogue score (VAS))
5. Completion rates of Patient complications up to 6 months post-randomisation (will be measured using patient complication Case report forms)
6. Completion rates of Work Productivity Impairment Questionnaire (WPAI) at baseline, 3 months and 6 months post-randomisation. (will be measured using the following questionnaires. Work Productivity Impairment Questionnaire (WPAI)
7. Patient and hospital reported resource use including referral rates for shoulder surgery at 6 months post-randomisation (will be measured using patient and hospital resource use case report forms)

Overall study start date
01/08/2021

Completion date
01/06/2023

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 18 years or above
3. Clinician believes the patient may benefit from corticosteroid treatment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Key exclusion criteria
1. Participants with a history of significant shoulder trauma (fracture or dislocation in last 5 years)
2. Previous shoulder surgery on the affected shoulder
3. Contraindications to APS therapy or CSI
4. A pre-existing neuro-degenerative and/or vascular condition that affects the function of the shoulder.
5. Received CSI/APS injection in 2 months prior to randomisation
6. The participant is unable to follow trial procedures
7. Patient does not have access to email/ smartphone directly or indirectly

Date of first enrolment
12/04/2022

Date of final enrolment
12/10/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Shaftesbury Medical Centre
78 Osmondthorpe Lane
Leeds
United Kingdom
LS9 9EF

Study participating centre
Healthshare
Manzil Way
Oxford
United Kingdom
OX4 1GE

Sponsor information

Organisation
University of Oxford

Sponsor details
Joint Research Office
1st floor, Boundary Brook House
Churchill Drive
Oxford
England
United Kingdom
OX3 7GB
-
ctrg@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/01/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. steve.gwilym@ndorms.ox.ac.uk
Any datasets provided will be de-identified, therefore consent will not be required from participants. The PIS has already specified this, so participants are aware of this data sharing possibility. Each request will be considered on a case-by-case basis by the CI.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	30/07/2021	15/09/2021	No	Yes
Protocol file	version 1.0	30/07/2021	15/09/2021	No	No
HRA research summary			28/06/2023	No	No
Protocol article		17/01/2024	18/01/2024	Yes	No
Results article		01/07/2024	22/07/2024	Yes	No