

SPIRIT. Shoulder pain: randomised trial of injectable treatments

Submission date 15/09/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 17/09/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/07/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

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

Contact information

Type(s)

Scientific

Contact name

Prof Steve Gwilym

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

294982

Protocol serial number

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 subacromial 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

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

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

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?
Results article		01/07/2024	22/07/2024	Yes	No
Protocol article		17/01/2024	18/01/2024	Yes	No
HRA research summary			28/06/2023	No	No
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
Study website	Study website	11/11/2025	11/11/2025	No	Yes