Participant Information Sheet

We would like to invite you to take part in a research study investigating two different types of treatment for your painful shoulder.

Before you decide to participate in the study, we would like you to understand why the study is being done, and what it will involve for you. Please read the following information carefully.

If there is anything that is not clear, or you would like more information, please ask us. Discuss it with friends and relatives if you wish, the research team are ready to answer any questions you have.

You are free to decide whether or not you wish to take part and can change your mind at any point.

Your decision will not affect the level of care you will receive.

What is the purpose of the study?

Shoulder pain is very common, and currently many different treatments are used to try and treat this pain. The most common are steroid injections, combined with physiotherapy but there have been questions about whether steroid injections are the best way to treat this condition, as there are concerns that they may weaken tendons. Healthcare workers are therefore looking for other safe and effective treatment options for this painful condition.

This has led to recent improvements in injectable treatments which are called 'biologic' injections. Although these treatments are found to be safe, they have never been tested in a trial to establish effectiveness for shoulder pain.

We would like to perform a trial to compare a biologic-injection treatment against steroid injections. The injection we aim to test involves taking a sample of your blood, extracting the parts of the blood which potentially contribute to reducing pain and inflammation and injecting it back into the shoulder to aid healing.

Before we conduct a larger study, we need to do this smaller study to see how quickly we can recruit patients and whether patients and healthcare staff are happy with how it works. If this study is successful, a larger trial will take place to test if the new type of injection is better than steroids for shoulder pain. If this turns out to be the case, then our trials could help more patients in the NHS with this painful condition.

Why have I been invited to take part?

You have been referred to us with a painful shoulder so are eligible to be a part of this study. We hope to recruit 50 patients with a similar type of pain to yours.

Do I have to take part?

No. It is entirely your decision whether you choose to take part or not. Throughout the study you are free to withdraw at any time, without giving a reason. Should you wish to withdraw, simply contact the trial manager or your local research team using the details at the end of this sheet.

A decision to withdraw at any time will not affect the standard of care you receive. However, we will not be able to remove the data we have already collected prior to your decision to withdraw.

What would taking part involve?

If you decide you would like to be involved in the study, you will be asked to sign a consent form. We will collect some basic information about you including contact details, a brief medical history, and details of the injury. We will then ask you to fill out a questionnaire requesting information about your shoulder function and how you were feeling before you developed this pain. This will take approximately 15-20 minutes to complete.

This study will use a process called randomisation to allocate you to your treatment. This means there should be similar people in each of the treatment groups to make sure any difference between the treatments is

not due to anything else, like their age, gender or where they live. This way we will know any difference we see is truly because of the treatment rather than anything else. A computer will allocate patients to one of the two treatments, so neither the patient, nurse or doctor make the decision.

As well as receiving physiotherapy as per your standard care, you will either be treated with an injection of:

(a) Biologic (concentrated substance from your blood) OR
(b) Steroid (an anti-inflammatory medication).

The usual standard care treatment for shoulder pain is steroids, the biologic injection is a relatively new treatment and not used widely across the NHS for this injury, however it is used for other joint injuries.

We will take a blood sample prior to the injection. If you are receiving the biologic injection, then we will concentrate the sample and re-inject the components that we believe may reduce pain and inflammation. If you receive the steroid injection a similar blood sample will also be taken, which will then be discarded. This is to ensure that you do not find out which treatment you have received. This is known as being "blinded" and is in place so that we do not influence your opinions about the treatment during your participation.

It also helps to reduce any bias in our research, making the results more reliable. If you would like to know what treatment you received, then we can tell you at the end of the study.

Will there be extra medical procedures?

Yes, a blood sample (55 ml, about 3 and a half tablespoons) will be taken as mentioned above.

We will not store your blood sample, and samples that are not used will be destroyed immediately.

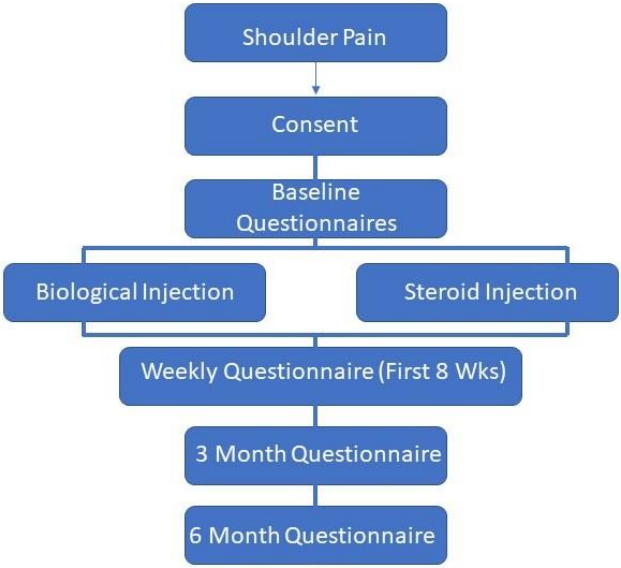
What happens during recovery?

After the injection you will be followed up according to the usual schedule at your health care provider, in the same way as patients who are not taking part in this trial. You will receive physiotherapy as per your standard care. The only additional commitment we ask is that you will complete a questionnaire at the following time-points during your recovery:

i. each week after your injection for the first 8 weeks;
ii. 3 months after your injection;
iii. 6 months after your injection.

The weekly questionnaire for the first 8 weeks will only ask you 1 brief question about how much pain you are experiencing. At 3 and 6 months we will send you a questionnaire with similar questions as those asked at the start of the study (pre-injection) which should take no more than 15-20 minutes to complete. We will send you a weblink to access the questionnaires electronically by email and/or text message, depending on your preference. We would appreciate completion of the questionnaires as soon as you receive them. If we haven't heard from you after a few days, we will send you reminder emails/text and we might phone you to make sure you are able to access and complete the questionnaires or if we have any queries about the information you have already provided. Alternatively,

if you have any difficulties with the completion of the questionnaires you can always call or email the research team (see details at the end of this document) who will be happy to help.



Will there be any side-effects?

After you receive your injection, you may find you experience mild to moderate pain local to the injection site.

In rare cases pro-longed pain may occur, if you experience this or infection symptoms; including fever or chills, body aches and pains, feeling tired or fatigued, coughing or sneezing,
digestive upset, such as nausea, vomiting, or diarrhoea or any other symptoms that gives you cause for concern; contact your clinical team for advice or treatment on [insert contact details here]

Pros and cons of taking part

Both treatments are used across the NHS so there is no specific advantage to you for taking part in the study. However, your participation would help us improve treatment for future patients with similar pain. The study may also provide information on the best use of resources within the NHS.

Both treatments are approved treatments and used in some NHS centres to treat shoulder pain, with the biologic injection being a more recent medication compared to the steroid injection. However, there is nothing experimental about the biologic injection. Steroid injections have been used for many years.

The rare risk of infection following an injection in both cases is the same.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford, as sponsor, is the data controller and is responsible for looking after your information and using it properly. We will use the minimum personally identifiable information possible. We will keep identifiable information about you for 12 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 3 years after the publication of the results of the study.

Responsible members of the University of Oxford and the relevant NHS Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Your data from the questionnaires will be sent to your trial team at the site where you were consented for the trial, in this way your doctor will have full oversight of the data in relation to your participation in the trial. Your personal data will only be used as we have explained in this information sheet. If you are concerned about how your personal data is being used, please contact the study team using the contact details at the end of this information sheet.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.admin.ox.ac.uk/individual-rights

The lawful basis for the processing of your personal data is governed by the UK General Data Protection Regulation (GDPR) and Data Protection Act (2018) Articles 6 & 9. The University of Oxford will not transfer your personal data to any third countries or international organisations.

When you agree to take part in a research study, de-identified research data may be provided to other researchers in this organisation and other organisations.

This information will not identify you and will not be combined with other information in a way that could identify you.

If you are concerned about how your personal data is being used, please contact the Chief Investigator/study team at: spirit@ndorms.ox.ac.uk

Who is running the study?

The study is funded by the Department of Health and Social Care and is the

work of Orthopaedic surgeons in Oxford and Leeds and sponsored by the University of Oxford.

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, a research group of the Nuffield Department of Rheumatology, Orthopaedics and Musculoskeletal Sciences (NDORMS).

The research team is qualified to do this study because they have all the relevant training and skills required. The team has a lot of experience in caring for patients with fracture injuries and are active in health research.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by the <XXX> Research Ethics Committee.

How have patients and the public been involved in creating this study?

Members of the public have been involved in the development of this study and are involved in its management. We value the patient perspective which has been key in the development of this research. Participants' views will continue to be represented throughout the study. The trial management committee that will regularly review the study progress, includes at least one patient representative who will be involved in discussion and decision-making throughout the duration of the study.

If you would like to know more about getting involved in research as a patient or member of the public, please see this link: https://www.nihr.ac.uk/patients-and-public/

What if new information becomes available during this study?

Sometimes during the course of a research study, new information becomes available about the treatment that is being studied. If this happens, the research team will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, we will encourage you to discuss your continued care with your doctor. If you decide to continue in the study, you may be asked to sign an updated electronic consent form.

What happens at the end of the study?

This study is expected to last 2 years. We will publish the findings at the end of the study in medical journals and present them at medical conferences. They will be made available on the study website. You will not be identified in any reports or publications.

Will I be reimbursed for taking part?

There is no financial reimbursement for your time, however there will be no additional costs to you for taking part. Your follow ups will be sent via text or email and can be completed at a time convenient to you. There are no additional visits to hospital or clinic required.

What if there is a problem?

The University of Oxford is the Sponsor for the study and has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in

respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Steve Gwilym who is the overall lead of this trial on spirit@ndorms.ox.ac.uk or 01865 223126; or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or email ctrg@admin.ox.ac.uk.

For independent advice, ask your treating health care centre for the contact details for the Patient Advice Liaison Service (PALS). PALS is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact <Insert PALS details>

Get in Touch

If, at any time, you would like further information about this study you may contact our Trial Management Team using the following details:

SPIRIT Trial Manager

01865 223126

spirit@ndorms.ox.ac.uk

Your Local Research Lead (insert name of local researcher)

(insert telephone number)

Email: (please complete)

Overall Lead of this Study: Prof Steve Gwilym

For further details of the study and our full privacy notice you can also refer to our trial website:https://www.ndorms.ox.ac.uk/clinical-trials/current-trials-and-studies/spirit