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SUBACROMIAL INJECTIONS FOR SHOULDER SUBACROMIAL PAIN SYNDROME – COMPARING ANTEROLATERAL VERSUS POSTERIOR APPROACH. A RANDOMISED CONTROLLED TRIAL.

MR JT HIRST, MR TA KWAEES, MR CP CHARALAMBOUS

27th March 2019

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DETAILS OF RESEARCHERS

MR JOHN TIMOTHY HIRST

SPECIALIST REGISTRAR

BLACKPOOL VICTORIA HOSPITAL, WHINNEY HEYS ROAD, BLACKPOOL, FY3 8NR

11 THE GREENACRES, LYMM, CHESHIRE, WA13 9NT

PERSONAL EMAIL: TIM.HIRST@DOCTORS.ORG.UK

NHS EMAIL: JOHN.HIRST@BFWHOSPITALS.NHS.UK

MOBILE: 07825690241

MR TARIQ KWAEES

SPECIALIST REGISTRAR

MERSEY DEANERY, REGATTA PALACE, BRUNSWICK BUSINESS PARK, SUMMERS ROAD, LIVERPOOL, L3 4BL

PERSONAL EMAIL: TARIQKWAEES@GMAIL.COM

NHS EMAIL: DR.KWAEES@BFWHOSPITALS.NHS.UK

MOBILE: 07553782778

MR CHARALAMBOS CHARALAMBOUS

CONSULTANT ORTHOPAEDIC SURGEON

BLACKPOOL VICTORIA HOSPITAL, WHINNEY HEYS ROAD, BLACKPOOL, FY3 8NR

FLAT 204, 159 HATHERSAGE ROAD, MANCHESTER, M13 0HX

PERSONAL EMAIL: BCHARALAMBOS@HOTMAIL.COM

NHS EMAIL: MR.CHARALAMBOUS@BFWHOSPITALS.NHS.UK

NHS PHONE: 01253 655 983

NHS FAX: 01253 306 817

MOBILE: 07712192409

1 Study Summary

Title	**Subacromial Injections for Shoulder Subacromial Pain Syndrome – Comparing Anterolateral Versus Posterior Approach**
Short Title	Anterolateral Versus Posterior Approach With Steroid Injection For Subacromial Pain Syndrome
Version & Date	Version six, 27st March 2019
Chief Investigator	Mr C.P Charalambous
Objectives	To determine if there is any difference in terms of pain relief in patients with shoulder subacromial pain syndrome, when given a steroid injection into the subacromial space via an anterolateral approach compared to a posterior approach.
Hypothesis	That there is no difference in terms of pain relief at 3 months, 6 months and 1 year from an injection via an anterolateral approach compared to one from a posterior approach
Methodology	Randomised controlled trial. Patients will attend the orthopaedic clinic and if diagnosed with shoulder subacromial pain syndrome, be offered a steroid injection based on clinical needs. If the patient consents to having a steroid injection, he/she will then be invited to participate in the trial – where they will have an injection by one of the two approaches. **Initial clinic assessment:** The data collected will include the following, • Which arm is afflicted by the syndrome • Left or right handed (i.e. which is the dominant arm) • Has the patient had previous steroid injection – if so, who by and when • Patient to answer an Oxford Shoulder Score (OSS) questionnaire (The questionnaire used for the study will be in the form of a modified OSS (i.e. In addition to the standard OSS we will inquire about general symptoms and signs (pain, stiffness), duration, hand dominance, previous injuries to the shoulder and previous treatments to the shoulder. (See attached questionnaire) • Patient also asked to complete Disabilitities of Arm, Shoulder and Hand (DASH) questionnaire and Short Form 36 Health Survey (SF36) **At the time of injection:** • Assessment of pain prior to injection using a visual analogue scale 0-10 (0=no pain, 10=severe pain) • Assessment of how uncomfortable the injection was using a visual analogue scale 0-10 (0=no discomfort, 10=extremely uncomfortable) • Assessment of pain 20-30mins after injection using a visual analogue scale 0-10 (0=no pain, 10=severe pain) • The injection: Given under sterile aseptic non-touch conditions. This is standard practice and is NOT formally part of the study (i.e. patients would be receiving the injection regardless of whether or not they were participating in the study). Please see below for details. **Follow up clinic assessment (3 months, 6 months and 1 year post injection):**

	• Assessment of pain at 3 months, 6 months and 1 year using a visual analogue scale 0-10 (0=no pain, 10=severe pain) • Patient to answer a modified oxford shoulder score (OSS) questionnaire (The follow up questionnaire will be identical to the initial questionnaire but excluding questions on previous treatments, hand dominance, injuries and duration. See attached questionnaire) at 3 months, 6 months and 1 year. • Patient to answer Disabilities of Arm, Shoulder and Hand (DASH) Questionaire and Short Form 36 (SF36) Health Survey (identical to the ones completed before the injection) at 3 months, 6 months and 1 year.
Duration	1 year follow up per patient. 36 months total study duration
Centres	One centre – Orthopaedic department, Blackpool Victoria hospital
Primary End Point	Improvement in the Oxford Shoulder Score (OSS) at 3 months
Secondary End Points	1. Oxford Shouldr Score (OSS) at 6 months and 1 year 2. Pain on visual analogue scale at 3 months, 6 months and 1 year 3. Disabilities of Arm, Shoulder and Hand (DASH) score at 3 months, 6 months and 1 year 4. Short form 36 (SF36) Health Survey at 3 months, 6 months and 1 year.
Participants	86 in total (43 for each approach) The study statistician has calculated the number of participants needed for the study, so that the study can reliably answer its aims, whilst avoiding wastage of time and resources. Statistical methods have been used for sample size calculation as follows: the standard deviation for change in Oxford Shoulder Score (OSS) at 12 weeks from baseline was obtained from a previous study of steroid injection for shoulder pain (Holt, TA et al[11]). 43 patients in each group are needed based on 80% power for a two sample t-test, detecting a minimal important difference of 6 and a two-tailed significance level of 0.05 with a standard deviation of 9.1. This accounts for 10% attrition between baseline and 3 months as documented in the previous study (Holt, TA et al[11]).
Inclusion Criteria	1. Patient diagnosed with shoulder subacromial pain syndrome 2. Age ≥ 18
Exclusion Criteria	1. Age < 18 2. Lacking capacity/unable to give valid consent for participation 3. Full thickness rotator cuff tear diagnosed on either Ultrasound scan or Magnestic Resonance Imaging 4. Unable to complete follow up 5. Unable to speak or read English
Statistical Analysis	A statistician has formally calculated the number of patients required for the study. Baseline demographic and clinical variables will be reported using summary statistics. In terms of the primary outcome, the change in total Oxford Shoulder Score from baseline to 3 months post-injection will be compared between the two groups using either the Independent Samples t-Test or Mann-Whitney U Test, with the final choice depending on

	an exploration of the data. The same approach will be adopted for secondary outcomes. All analysis will be performed according to the intention to treat principle.

1.1 Flowchart of Treatment Schedule

- STEP 1 - New diagnosis of Shoulder Subacromial Pain Syndrome

Patient presents to orthopaedic outpatient clinic and is diagnosed as having shoulder subacromial pain syndrome, offered and agrees to have a steroid injection

- STEP 2 – Does patient meet inclusion criteria?

NO – does not enter study

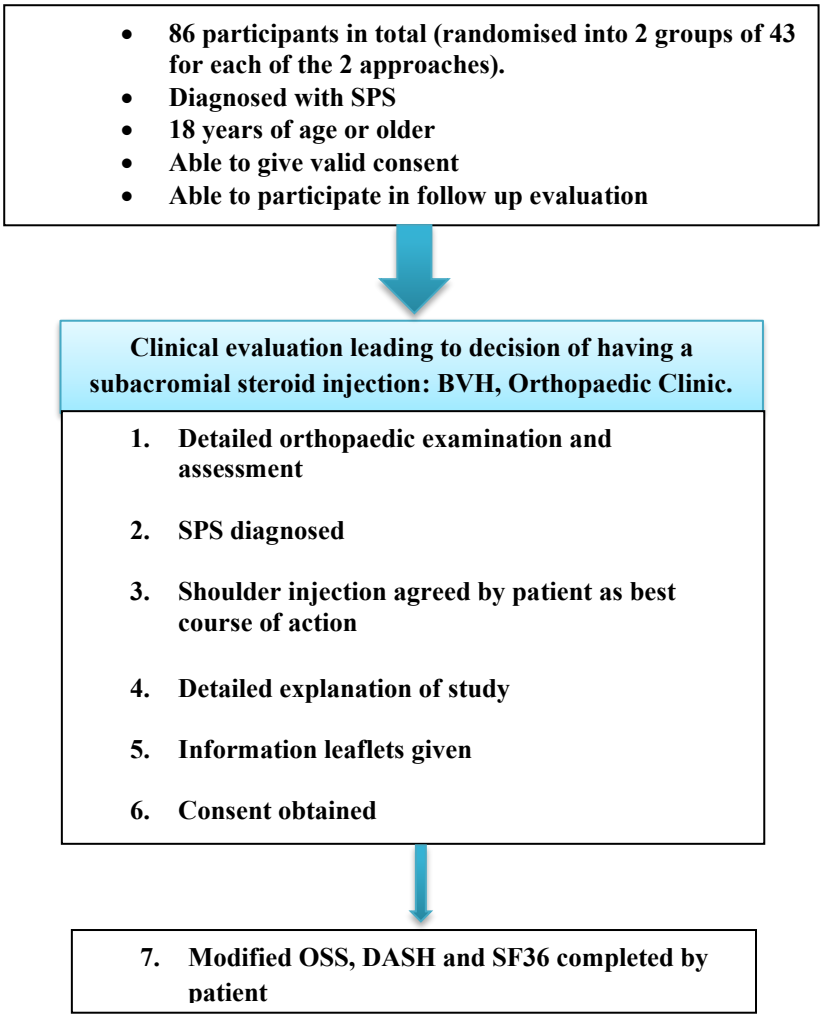
YES – patient initiated to enter study

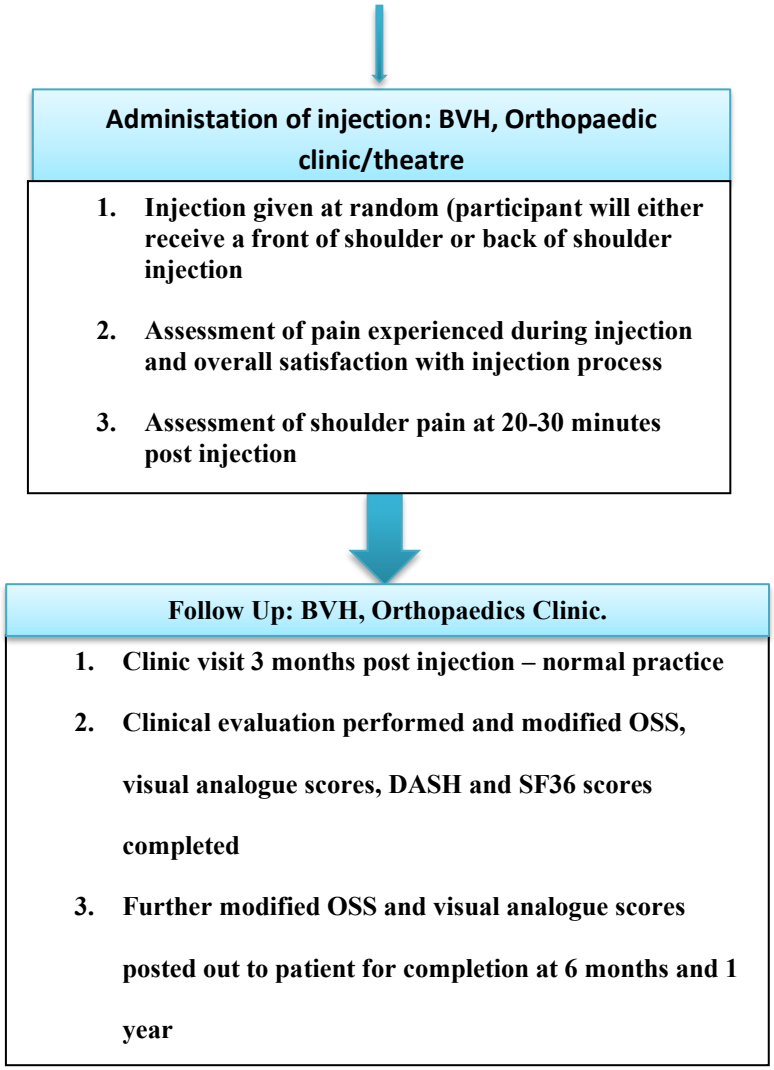
- STEP 3 – Patient consent and study schedule

Patient agrees and consents – patient participates in study. They will be seen in outpatient clinic approximately 3 months following the injection. Postal questionaires will be sent out at 6 months and 1 year.

Patient does not agree or consent – patient does not enter study

- Please see flow chart below





2 Overview

Patients who present with subacromial pain syndrome (disorders such as subacromial bursitis, rotator cuff tendinopathy, calcific tendinitis, subacromial inflammation with a partial thickness rotator cuff tear) to the orthopaedic outpatient clinic are treated initially with a subacromial steroid injection in addition to physiotherapy for a period of 3 months. This applies to patients who have had no other treatments previously as well as to patients who have had previous physiotherapy or steroid injections prior to presentation. Patients who do not want to undergo the treatment offered are either treated with simple analgesia, sole physiotherapy or surgery.

When a patient with one of the above conditions agrees to go ahead with a steroid injection followed by physiotherapy, the steroid injection is given at the earliest opportunity. The steroid injection is given into the subacromial space either using the anterolateral (front-side) approach (1 cm below and behind the anterior edge of the acromion with the needle aiming towards the under surface of the acromion) or using the posterior (back-side) approach (1cm inferior and medial to the posterlateral acromial edge with the needle pointing towards the anterolateral aspect of the acromion). The exact approach is determined according to the preference of the person carrying out the injection. As a routine we use a 10ml syringe containing 10mls of 0.25% Marcaine along with 40mg triamcinolone with an 18 gauge (green) needle. It is normal for patients to complain of some discomfort during the injection. If a patient experiences any significant discomfort or they

cannot tolerate the injection for whatever reason, then the injection is discontinued and is not reattempted using a different approach.

Following the injection, patients are questioned on any discomfort experienced during the injection and on whether or not their pain has improved. They are then taken through a protocol of physiotherapy for their shoulder over the subsequent 3 months. A protocol is issued for guidance however therapists are allowed to use other modalities as per their discretion. The frequency of appointments with physiotherapy will depend on patient's symptoms as well as their progression. For study purposes a frequency record of these meetings will be kept and matched to the overall OSS. Patients are seen routinely in 3 months following an injection in order to assess any improvement in symptomatology using the OSS, visual analogue score, DASH and SF36 questionaires. If the symptoms have improved then no further intervention is taken. Further OSS, visual analogue pain score, DASH and SF36 questionaires will be posted out at 6 months and 1 year. On the other hand, if they are still troubled with symptoms then the possibility of further injections or surgery is discussed.

The aim of this study is to compare the two approaches that are currently used for subacromial steroid injections, namely the anterolateral and posterior approach, with regards to their effectiveness in improving shoulder symptoms. There will be no deviation from our routine protocol other than randomising patients who agree to participate in this study to either the anterolateral or posterior approach.

In summary, it is patients who are seen in clinic with a subacromial pathology and subsequently diagnosed with shoulder subacromial pain syndrome, who are offered an injection. Those who agree to have an injection will then be invited to participate in the study. An information leaflet will be given to all potential participants and they will be allowed sufficient time to read through it, digest all the information and ask any questions they may have before making a decision regarding their participation. Those who agree to participate will be randomly allocated, using sealed envelopes to one of the two approaches for the injection. The injection will then be administered via the selected approach by a clinician who is qualified in carrying out the procedure. Patients will be asked about any discomfort experienced during the injection, improvement in pain following the injection prior to leaving hospital and overall satisfaction with the injection. Following this patients will have physiotherapy as an outpatient as routine and will be seen at about 3 months post injection for a further assessment at the clinic. Again the shoulder assessment will be repeated on that occasion. Shoulder assessment questionaires will be posted out for completion at 6 months and 1 year (OSS, pain on visial analogue scale, DASH and SF36) There will be no change in patients care from routine practice other than the randomisation of the approach used for the injection. Patients who are invited to participate in the study and agree to participate will have their GP informed of their participation.

Assessments

1. Prior to injection: assessment of pain using a visual analogue score, clinical assessment of shoulder movement and completion of a modified Oxford Shoulder Score, Disabilities of Shoulder, Arm and Hand questionaires and Short Form 36 Health Survey.

2. 20-30 minutes Post injection: assessment of pain using a visual analogue score

3. Prior to leaving hospital: pain experienced during the administration of the injection and the overall satisfaction with the injection

4. 3 months post injection: assessment of pain using a visual analogue score, clinical assessment of shoulder movement and completion of a modified Oxford Shoulder Score, Disabilities of Shoulder, Arm and Hand questionaires and Short Form 36 Health Survey.

5. 6 months and 1 year post injection: assessment of pain using visual analogue score and completion of a modified Oxford Shoulder Score, Disabilities of Shoulder, Arm and Hand questionaires and Short Form 36 Health Survey via post.

The main outcome for this study will be the Oxford Shoulder Score (OSS) at 3 months post-injection. In addition to the standard OSS, the questionnaire will inquire about general symptoms and signs, duration, hand dominance, previous injuries to the shoulder and previous treatments to the shoulder. The follow up questionnaire will be identical to the initial questionnaire but excluding questions on previous treatments, hand dominance, injuries and duration. (See attached questionnaires).

Other demographics that will be recorded on the pre-designed pro forma include: number and frequency of physiotherapy sessions pre and post injection, and subsequent need for further management (see attached)

Hard copies of data (questionnaires and forms) collected will be placed into the patient's notes. At the same time this data will be recorded electronically on an Excel database and saved on an encrypted, password protected memory stick. This memory stick will be stored in a locked filing cabinet in the orthopaedic department at Blackpool Victoria Hospital. Please note: The electronic data will contain NO identifiable information. Participants will be identified by a unique study I.D number which can only be linked to them by members of the research team.

2.1 Background

Shoulder pain is a very common symptom. It has been reported that approximately 15 patients per 1000 present to their GP with shoulder pain every year [1]. Shoulder pain, inflammation and difficulty performing overhead activities are some of the symptoms associated with subacromial pathology [2]. Injections are a very common treatment for subacromial pathology [3]. These injections are given by general practitioners, physiotherapists, rheumatologists and orthopaedic surgeons [4-6]. If we can identify factors that improve the efficiency of these injections then this will be of great value. Previous studies have looked at the accuracy of various approaches for injections in terms of where the needle tip is and where the local anaesthetic is administered [7-10]. However, there has been no previous study, to our knowledge, that has examined the clinical outcome of the various approaches.

2.2 Study Objectives

The aim is to determine if there is any difference in the effectiveness of a steroid injection, given for Shoulder Subacromial Pain Syndrome, when it is administered via an anterolateral as compared to a posterior approach. Here effectiveness is measured in terms of improvement in pain and function.

Primary outcome is improvement in the modified Oxford Shoulder Score at 3 months post-injection.

Our hypothesis is that there is no difference in improvement of pain with an injection given via an anterolateral approach compared to posterior approach.

3 Study Design

3.1.1 General

The study will be a randomised controlled trial.

Estimated duration is 36 months (12-18 months for patient recruitment, 12 months for follow up and data collection and analysis, 6 months for write up and publication).

3.1.2 Study procedure

Patients who present to the orthopaedic outpatient department and are subsequently diagnosed with Shoulder Subacromial Pain Syndrome will be treated with a steroid injection along with a course of physiotherapy for a period of 3 months. This is routine practice.

Potential participants will be given an information leaflet (please see appendix 1) to keep and read for as long as required, and will also receive a verbal explanation by the consultant in order to reach a decision about taking part. If the patient agrees to participant in the study he/she will be asked to sign a consent form indicating they have understood all details of the study. This form will also be signed by the researcher (please see appendix 2). Arrangements are then made for the administration of the injection.

The steroid injection will be administered into the subacromial space (this is the anatomical space through which the shoulder tendons run. It is situated between part of the scapula bone called the acromion and the long humerus bone of the upper arm) using one of the following:

1. Anterolateral approach - 1 cm below and behind the anterior edge of the acromion with the needle aiming towards the undersurface of the acromion.
2. Posterior approach - 1cm inferior and medial to the posterolateral acromial edge with the needle pointing towards the anterolateral aspect of the acromion.

As a routine we use a 10ml syringe containing 10mls of 0.25% Marcaine (local anaesthetic) along with 40mg triamcinolone cream (steroid). An 18 gauge (green) needle is used to enter the shoulder.

Patients will be allocated at random, using pre-sealed envelopes, to one of the two approaches. These will be opened immediately prior to the injection which will be administered by a clinician who is skilled in carrying out the injection (see below for more details on randomisation). Patients will then be questioned on the experience of the injection in the form of pain experienced during administration and overall satisfaction of the experience before leaving hospital and shoulder pain will be assessed following the injection by the visual analogue pain scale.

Patients will then have physiotherapy for their shoulder as an outpatient (see attached) and will be seen at 3 months post injection for a follow up assessment.

Assessments (please see appendix 3 and 4)

1. Prior to injection: assessment of pain using a visual analogue score, clinical assessment of shoulder movement and completion of a modified Oxford Shoulder Score, Disabilities of Shoulder, Arm and Hand questionaires and Short Form 36 Health Survey.

2. 20-30 minutes Post injection: assessment of pain using a visual analogue score

3. Prior to leaving hospital: pain experienced during the administration of the injection and the overall satisfaction with the injection

4. 3 months post injection: assessment of pain using a visual analogue score, clinical assessment of shoulder movement and completion of a modified Oxford Shoulder Score, Disabilities of Shoulder, Arm and Hand questionaires and Short Form 36 Health Survey.

5. 6 months and 1 year post injection: assessment of pain using visual analogue score and completion of a modified Oxford Shoulder Score, Disabilities of Shoulder, Arm and Hand questionaires and Short Form 36 Health Survey via post.

Hard copies of data (questionnaires and forms) collected will be placed into the patient's notes. At the same time this data will be recorded electronically on an Excel database and saved on an encrypted, password protected memory stick. This memory stick will be stored in a locked filing cabinet in the orthopaedic department at Blackpool Victoria Hospital. Please note: The electronic data will contain NO identifiable information. Participants will be identified by a unique predetermined study I.D number which can only be linked to them by members of the research team.

3.2 Primary Study Endpoints

Primary end point will be improvement in Oxford Shoulder Score at 3 months post-injection

3.3 Secondary Study Endpoints

Secondary end points include Oxford Shouldr Score (OSS) at 6 months and 1 year, pain on visual analogue scale at 3 months, 6 months and 1 year, Disabilities of Arm, Shoulder and Hand (DASH) questionnaire at 3 months, 6 months and 1 year and Short Form 36 (SF36) Health Survey at 3 months, 6 months and 1 year.

3.4 End of study

Total duration of the study will be 36 months. This includes participant selection, data collection/analysis and publication of findings. For each participant the duration of participation will be 1 year.

3.5 Subject Selection and Withdrawal

Subjects will be identified on presentation to the orthopaedic outpatient clinic of Mr CP Charalambous. Patients will be free to withdraw from the study at any time without prior warning and without prejudice, participation will be entirely voluntary. Patients will be asked to sign a consent form indicating they have understood this.

3.5.1 Inclusion Criteria

1	Patient diagnosed with shoulder subacromial pain syndrome
2	Age ≥ 18
3	Capacity to give valid consent for participation
4	Able to complete the follow up

3.5.2 Exclusion Criteria

1	Age < 18
2	Lacking capacity/unable to give valid consent for participation

3	Full thickness rotator cuff tear diagnosed on either Ultrasound scan or Magnestic Resonance Imaging
4	Unable to complete follow up
5	Unable to speak or read English

3.6 Subject Recruitment and Screening

Potential study subjects will be assessed by a trained clinician in the Orthopaedic outpatient clinic, where a diagnosis of Shoulder Subacromial Pain Syndrome will be made. Information on the study will be given to the patients in the form of a leaflet and verbal explanation by the consultant. They will be allowed to read and digest the information for as long as required as well as ask any questions they may have before agreeing to take part.

No vulnerable groups will be involved.

3.7 Randomisation Process

Patients will be randomised by the selection of sealed envelopes with one of the two approaches listed inside. There will have 86 envelopes, 43 containing the anterolateral approach and 43 containing the posterior approach. The envelopes will be generated in advanced by the research team and will be unidentifiable once sealed. They will be allocated at random to the 86 participants. The envelopes will be kept in a locked filing cabinet in the orthopaedic department and once opened, the contents will be filed in the patients notes.

3.8 Informed Consent

Informed consent will be obtained during the initial clinic visit after the patient has had adequate time to read the information leaflet, digest the information provided and ask any questions they may have, as well as express their views/wishes. The patient will be asked to sign a consent form indicating they have understood all aspects of the study and their rights. This form will also be signed by the researcher and three copies of this form will be obtained (one for patient, one for researchers which will be stored in the study site file and one for the clinical notes).

Withdrawal of Subjects

Patient will be free to withdraw from the study at any time without explanation and without prejudice. A patient will be withdrawn from the study, if unable to tolerate the injection or does not comply with physiotherapy. Abrupt termination of patient from study will not put the patient at risk. The patient will still be offered care as they would be routinely, if unable to continue in study for whatever reason.

If patient fails to attend the follow up clinic visit then a letter will be sent to the patient and copied to the GP as is done routinely when a patient does not attend. A follow up appointment will then be booked for the nearest possible date.

4 Prior and Concomitant Therapy

There are no restrictions to prior or concomitant medicines permitted during the study.

The only therapy that patients will receive will be physiotherapy.

5 Laboratory Assays

Not applicable

6 Study Procedures

All relevant procedures are detailed above.

7 Statistical Plan

The study statistician has calculated the number of participants needed for the study, so that the study can reliably answer its aims, whilst avoiding wastage of time and resources. Statistical methods have been used for sample size calculation as follows: the standard deviation for change in Oxford Shoulder Score (OSS) at 12 weeks from baseline was obtained from a previous study of steroid injection for shoulder pain (Holt, TA et al[11]). 43 patients in each group are needed based on 80% power for a two sample t-test, detecting a minimal important difference of 6 and a two-tailed significance level of 0.05 with a standard deviation of 9.1. This accounts for 10% attrition between baseline and 3 months as documented in the previous study (Holt, TA et al[11]).

Baseline demographic and clinical variables will be reported using summary statistics. In terms of the primary outcome, the change in total Oxford Shoulder Score from baseline to 3 months post-injection will be compared between the two groups using either the Independent Samples t-Test or Mann-Whitney U Test, with the final choice depending on an exploration of the data. The same approach will be adopted for secondary outcomes. All analysis will be performed according to the intention to treat principle.

8 Safety and Adverse Events

There is no deviation in normal practice with regards to the medication being given, therefore standard pharmacovigilance procedures will be used.

8.1 Recording of Adverse Events

All Adverse Events (AE) Serious Adverse Events (SAE) will be recorded according to the R&D Office Procedure and the Trust Policy on Incident Reporting.

All adverse events occurring during the study period will be recorded. The clinical course of each event will be followed until resolution, stabilisation, or until it has been determined that the study treatment or participation is not the cause. Serious adverse events that are still on going at the end of the study period will be followed up to determine the final outcome.

No adverse events are anticipated in this study.

9 Data Handling and Record Keeping

9.1 Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Data Protection Act and UK Policy Framework for Health and Social Care Research (2017). Details collected will include answers to the patient proforma, Oxford Shoulder Score, clinical examination details and radiographs. Patient answers to proforma, the shoulder score and clinical examination details will be kept in the patient notes and also recorded onto an encrypted memory stick. Members of the research team and other health care

professions involved in the patient's care will be able to access the patient's clinical notes. Information recorded onto the encrypted memory stick will only be accessible by the research team. This memory stick will be stored in a locked filing cabinet in the orthopaedic department at Blackpool Victoria Hospital. Data will be anonymised on the memory stick by the use of unique ID number that will not identify the patient unless cross referenced by the overall code.

The Principal Investigator, Mr Charalambous, is the custodian of the data.

9.2 Case Report Forms

Applicable

9.3 Records Retention

Patient forms and consent forms will be stored in patient's notes and kept secure as per any set of NHS notes. Data recorded on encrypted memory stick will be stored until study is published in a scientific journal. This will be within a maximum of 5 years after which all such data will be permanently destroyed.

10 Study Monitoring, Auditing, and Inspecting

The investigator will permit study-related monitoring, audits and inspections by the Ethics Committee, the Sponsor and the Research Governance Manager.

Participation as an investigator in this study implies adherence to the principles and responsibilities of the UK policy framework, ICH/GCP and Directive 2000/20/EC

11 Ethical Considerations

This study will be conducted according to the standards of International Conference on Harmonization, Good Clinical Practice Guideline, Research Ethics Committee regulations, any applicable government regulations, Trust and Research Office policies and procedures.

This protocol and any amendments will be submitted to a properly constituted Research Ethics Committee (REC) through the Health Research Authority (HRA) for approval of the study conduct.

No research studies can commence until the chief investigator has received approval from the Trust issued by the Research and Development office and a letter confirming HRA validation approval (both assessment and ethical validation).

Undertaking a research study without the written approval from the HRA or if carried out in breach of the UK policy framework will lead to disciplinary action.

11.1 Patient information Sheets

Patients will be given the information sheet detailing the study (please see appendix 1). GPs (please see appendix 5) will be contacted informing them of the diagnosis, participation in the study, intervention given and follow up.

12 Study Finances

12.1 Funding

The study will not be deviating from routine practice provided in the NHS for such patients. The only funding required (£337 has been applied for and approved for sponsorship by the Blackpool Teaching Hospitals NHS Foundation Trust Research and Development committee) will cover the printing costs relating to the study, and the costs of envelopes and postage relating to the follow up questionnaires.

12.2 Indemnity

No further indemnity has been applied for. NHS indeminity will apply.

13 Sponsorship:

This study will be sponsored by Blackpool Teaching Hospitals NHS Foundation Trust Publication Plan

The results of the study will be published in a peer reviewed orthopaedic journal. All data will be fully anonymised hence no identifiable information will be published. The results of the study will also be presented in medical and surgical conferences in the form of PowerPoint presentations and/or poster presentations. Again, no identifiable/personal data will be included in such presentations as all data will be anonymised. Results from the study will be used to influence future care for patients with Shoulder Subacromial Pain Syndrome.

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Appendix 1 – Information Sheet

PARTICIPANT INFORMATION SHEET

Study Title: Subacromial Injections For Shoulder Subacromial Pain Syndrome – Comparing Anterolateral Versus Posterior Approach;

A Randomised Controlled Trial.

Researchers: JT Hirst, T Kwaees, CP Charalambous.

IRAS number: 249246

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with us if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this document.

What is the purpose of the study?

This study aims to determine if there is any difference, in terms of pain relief for shoulder subacromial pain syndrome (where tendons in the shoulder are irritated when passing through a narrow space), between giving a steroid injection on the front (anterior) side of the shoulder and giving the same injection on the back (posterior) side of the shoulder.

Why have I been chosen?

You have been chosen because you have been diagnosed with shoulder subacromial pain syndrome – a condition where there is inflammation in the subacromial space, the space in the shoulder, through which tendons that are connected to muscles around the shoulder pass through. Your surgeon has recommended having a steroid injection into this space to treat this condition. Please see Patient UK information leaflet on 'Rotator Cuff Injury and Inflammation' for more information on subacromial pain syndrome.

Do I have to take part?

Participation is voluntary; it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still free to withdraw at any time or a decision not to take part will not affect the standard of care you receive in the long term.

What will happen to me if I take part?

You will be given a steroid injection into the subacromial space by one of the two approaches. This will be decided at random, so you have a 50-50 chance of having either the front or back approach. You will then be asked to return to clinic in 3 months time for a follow up appointment, where you will be asked how you are doing and your shoulder will be examined. This is exactly the same as if you were having a steroid injection for this condition and were not taking part in the trial – as all patients are followed up in 3 months time. We will also contact your GP to request reports of any previous physiotherapy sessions you have undertaken.

What do I have to do?

Prior to the injection, you will be required to complete a questionnaire about your shoulder pain and shoulder history. Once given the injection you will be then asked 3 further questions before leaving hospital. You will then be asked to attend a follow up appointment at the same clinic in 3 months time. On this follow up visit you will be asked to fill in a second questionnaire about your shoulder pain and any improvement. After this we will ask you to fill in a third and fourth questionnaire about your shoulder pain and any improvement at 6 months and 1 year and these will be sent out to you by post.

What is the procedure that is being tested?

The procedure being tested is the way which the injection is given. We are testing whether an injection given from the front of the shoulder provides better pain relief for shoulder subacromial pain syndrome than an injection given into the back of the shoulder.

What are the alternatives for treatment?

The alternatives include rest with simple painkillers, physiotherapy and surgery. You will not be asked to take part in this study if the surgeon does not feel that a steroid injection is the best treatment for your condition.

What are the side effects of any treatment received when taking part?

Side effects are related to the procedure of having an injection but not related to the different approaches (front versus back). Side effects of having a steroid injection include infection, allergic reaction, aggravation of pain and symptoms and failure to relieve pain.

What are the possible disadvantages and risks of taking part?

We are not aware of any disadvantages of taking part. The only risks include those possible side effects mentioned above. These risks are not related to the trial but to any injection. The surgeon will explain these risks before giving you the injection.

What are the benefits of taking part?

The research may benefit you or future patients because the findings will inform treatment in the future. We hope to determine if one approach is better than other.

What if new information becomes available?

We will inform you if any new information becomes available while you are taking part in the study.

What happens when the research study stops?

You will be continued to be cared for under standard treatment by the NHS.

What if something goes wrong?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanism should be available to you. Patient advice and liaison service (PALS) contact information:
PALS, Blackpool, Fylde and Wyre Hospitals NHS Foundation Trust, Home 2, Victoria Hospital, Whinney Heys Road, Blackpool, Lancashire, FY3 8NR
01253 955588 / 01253 955589

Will my taking part in this study be kept confidential?

All information, which is collected, about you during the course of this research will be kept strictly confidential. Any information about you, which leaves the hospital, will have your name and address removed so that you cannot be recognized from it. When a scientific paper is written about the results you will not be identified in any way.

What will happen to the results of the research study?

The results of the study will be published in a scientific paper. A lay summary will be available and can be requested at the time of signing the consent form.

Who is funding this study?

This study is funded by Blackpool, Flyde and Wyre Hospitals NHS Foundation Trust.

Who has reviewed this study?

The Blackpool Teaching Hospitals NHS Trust local Research and Development Department ethics committee have reviewed this study.

General Data Protection Regulation (GDPR)

Blackpool, Flyde and Wyre Hospitals NHS Foundation Trust is the sponsor for this study. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. We will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Individuals from Blackpool, Flyde and Wyre Hospitals NHS Foundation Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

You can find out more about how we use your information by contacting the Research and Development Department at Blackpool Victoria Hospital.

Contact for further information.

1. Mr CP Charalambous, Consultant Orthopaedic Surgeon, Orthopaedic Department, Blackpool Victoria Hospital, Whinney Heys Road, Blackpool, Lancashire, FY3 8NR
   Tel: 01253 655983 Fax: 01253 303530

3. Research and Development Department, Blackpool Victoria Hospital, Whinney Heys Road, Blackpool, Lancashire, FY3 8NR.
   Tel: 01253 951514

If you would like some general information about being involved in a research project please contact your local Research & Development Department on 01253 951514 or see www.nres.org.uk or www.involve.org.uk

Thank you for taking the time to read about this study, if you have any questions please do not hesitate to ask. If you agree to take part you will be given a copy of this information sheet as well as the consent form for taking part in the study.

Appendix 2 – Patient Consent Form

CONSENT FORM

Title of Project: Subacromial Injections for Shoulder Subacromial Pain Syndrome – Comparing Anterolateral vs Posterior Approach; a Randomised Controlled Trial.

Centre Name: Blackpool Victoria Hospital

IRAS number: 249246

Patient Identification Number for this trial:

Name of Researchers: John Timothy Hirst, Tariq Kwaees, Bambos Charalambous

Please tick the box:

I confirm that I have read and understood the information sheet dated MARCH 2018 (Version 5) for the above study and have had the opportunity to ask questions. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

I understand that sections of any of my medical notes may be looked at by responsible individuals from Blackpool Teaching Hospitals or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

I agree that my GP be contacted and informed of my participation in the above study. ☐

I agree for my GP to be contacted about previous physiotherapy treatment I may have received for my shoulder ☐

I agree to take part in the above study. ☐

I agree for the use of anonymised quotations to be published in scientific articles ☐

I wish to receive a lay summary of the results of the study ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from Researcher)	Date	Signature
_____	_____	_____
Researcher	Date	Signature

Appendix 3 – Initial Visit Proforma

Subacromial Injections for Shoulder Subacromial Pain Syndrome – Comparing Anterolateral vs Posterior Approach; a Randomised Controlled Trial.

QUESTIONNAIRE FOR INITIAL CLINIC VISIT

Authors: JT Hirst, T Kwaees, CP Charalambous

Identification number:

Date:

Please complete all the questions that follow. If you need any assistance or help completing the questionnaire, please do not hesitate in asking one of the members of staff at the clinic who will be happy to help.

Please answer the following questions to the best of your ability.

1. Which shoulder is it that you are having symptoms from? RIGHT / LEFT

2. Are you RIGHT or LEFT handed? RIGHT / LEFT

3. How long have you had pain in your shoulder? ☐ 1- 3 months ☐ 3-6 months ☐ 6-12 months ☐ >12months

4a. Have you had an injury to the shoulder recently or in the past? YES/NO (if no please proceed to question 5a)

4b. If yes, when_____ and how?_____

_____

5a. Have you had any previous physiotherapy to this shoulder? YES/NO (if no please proceed to question 6a)

5b. If yes, when?_____

5c. If yes, for how long? _____

6a. Have you had any previous steroid injection(s) to this shoulder? YES/NO (if no please proceed question 7a)

6b. If yes, how many? _____

6c. When was the last injection? _____

6d. Who gave this last injection?

GP ☐ Nurse Practitioner ☐ Physiotherapist ☐

Surgeon ☐ Rheumatologist ☐ Other Doctor ☐

Other, please give details: _____

7a. Have you had any other treatment to this shoulder? YES/NO (if no please proceed to question 8a)

7b. If yes, what? _____

8a. Have you been taking any pain relief for your shoulder symptoms? YES/NO (if no please proceed to question 9)

8b. If yes please give details below.

Medication	**How long have you used this? (please tick the correct box)**							
Creams	☐	1-3 months	☐	3-6 months	☐	6-12 months	☐	>12 months ☐
Paracetamol	☐	1-3 months	☐	3-6 months	☐	6-12 months	☐	>12 months ☐
Ibuprofen	☐	1-3 months	☐	3-6 months	☐	6-12 months	☐	>12 months ☐

Tramadol	☐	1-3 months	☐	3-6 months	☐	6-12 months	☐	>12 months	☐
Patches	☐	1-3 months	☐	3-6 months	☐	6-12 months	☐	>12 months	☐
Other	☐	**Give details:**							

For the next question, please make a X on the line that matches to your response.

9. How much pain do you get from your shoulder overall?

No pain _____ Worst pain

<u>For the next 12 questions, please circle the appropriate response</u>

10. During the past 4 weeks how would you describe the worst pain you had from your shoulder?

None Mild Moderate Severe Unbearable

11. During the past 4 weeks have you had any trouble dressing yourself because of your shoulder?

No trouble A little bit of trouble Moderate Trouble Extreme Difficulty Impossible to do

12. During the past 4 weeks, have you had any trouble getting in and out of a car or using public transport because of your shoulder?

No trouble A little bit of trouble Moderate Trouble Extreme Difficulty Impossible to do

13. During the past 4 weeks in relation to your shoulder, have you been able to use a knife and fork, at the same time?

Yes,easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

14. During the past 4 weeks could you do the household shopping on your own?

Yes,easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

15. During the past 4 weeks could you carry a tray containing a plate of food across a room?

Yes,easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

16. During the past 4 weeks could you brush/comb your hair with the affected arm?

Yes,easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

17. During the past 4 weeks how would you describe the pain you <u>usually</u> had from your shoulder?

None Very Mild Mild Moderate Severe

18. During the past 4 weeks could you hang your clothes up in a wardrobe, using the affected arm?

Yes,easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

19. During the past 4 weeks have you been able to wash and dry yourself under both arms?

Yes,easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

20. During the past 4 weeks how much has pain from your shoulder interfered with your usual work (including housework)?

Not at all A little bit Moderately Greatly Totally

21. During the past 4 weeks have you been troubled by pain from your shoulder in bed at night?

No nights Only 1 or 2 nights Some nights Most nights Every night

The next three questions should be answered after having the injection. Again, please mark an X on the line that matches to your response.

24. How much pain did you experience during administration of the injection?

No pain _____ Worst pain

25. How severe is the pain in your shoulder now (20-30 minutes after having the injection)?

No pain _____ Worst pain

26. Overall how satisfied are you with the injection today?

Not satisfied _____ Very satisfied

This is the end of all questions. Please check back that you have answered every question.

Finally, thank you for your time in completing this questionnaire. You can now leave it with a member of staff.

Appendix 4 – Follow up visit proforma

Subacromial Injections for Shoulder Subacromial Pain Syndrome – Comparing Anterolateral vs Posterior Approach; a Randomised Controlled Trial.

QUESTIONNAIRE FOR FOLLOW UP CLINIC VISIT

Authors: J T Hirst, T Kwaees, C P Charalambous

Identification number:

Date:

Please complete all the questions that follow. If you need any assistance or help completing the questionnaire, please do not hesitate in asking one of the members of staff at the clinic who will be happy to help.

For this questions, please think about how your shoulder is since the injection 3 months ago and mark an X on the line that matches your response.

1. How much pain do you get from your shoulder overall?

No pain _____ Worst pain

For the final 12 questions, please circle the appropriate response.

2. During the past 4 weeks how would you describe the worst pain you had from your shoulder?

None Mild Moderate Severe Unbearable

3. During the past 4 weeks have you had any trouble dressing yourself because of your shoulder?

No trouble A little bit of trouble Moderate Trouble Extreme Difficulty Impossible to do

4. During the past 4 weeks, have you had any trouble getting in and out of a car or using public transport because of your shoulder?

No trouble A little bit of trouble Moderate Trouble Extreme Difficulty Impossible to do

5. During the past 4 weeks in relation to your shoulder, have you been able to use a knife and fork, at the same time?

Yes,easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

6. During the past 4 weeks could you do the household shopping on your own?

Yes,easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

7. During the past 4 weeks could you carry a tray containing a plate of food across a room?

Yes,easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

8. During the past 4 weeks could you brush/comb your hair with the affected arm?

Yes,easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

9. During the past 4 weeks how would you describe the pain you <u>usually</u> had from your shoulder?

None Very Mild Mild Moderate Severe

10. During the past 4 weeks could you hang your clothes up in a wardrobe, using the affected arm?

Yes,easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

11. During the past 4 weeks have you been able to wash and dry yourself under both arms?

Yes,easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

12. During the past 4 weeks how much has pain from your shoulder interfered with your usual work (including housework)?

Not at all A little bit Moderately Greatly Totally

13. During the past 4 weeks have you been troubled by pain from your shoulder in bed at night?

No nights Only 1 or 2 nights Some nights Most nights Every night

This is the end of all questions. Please check back that you have answered every question.

Finally, thank you for your time in completing this questionnaire. You can now leave it with a member of staff.

FOR CLINICIAN TO COMPLETE:

What was the decision regarding further management?

Please indicate out of the following:

1. Has the patient had any physiotherapy since the injection?

2. If so when and for how long?

Further management plan:

3. No further treatment

4. Continue with physiotherapy

5. State number of episodes of physiotherapy so far

6. Listed for surgery

7. Further injection

Appendix 5 – GP template letter

Mr Charalambos Charalambous
Department of Trauma and Orthopaedics
Blackpool Victoria Hospital
Whinney Heys Road
Blackpool
Lancashire
FY3 8NR
United Kingdom
Email: mr.charalambous@bfwhospitals.nhs.uk
Phone: 01253 655 983
Fax: 01253 306 817

GP address.

Date:

Dear Doctor

Insert Patients details:

Diagnosis: Subacromial Subacromial Pain Syndrome

Study Name: **Subacromial Injections for Shoulder Subacromial Pain Syndrome – Comparing Anterolateral vs Posterior Approach; a Randomised Controlled Trial.**

IRAS number: 249246

The above patient was seen in my clinic on [insert date] for shoulder pain. After discussing the possible treatment options with the patient, a subacromial steroid injection was opted for as the treatment of choice followed by physiotherapy.

I am carrying out a randomised controlled trial investigating if there is any difference in pain relief if the injection is given via two different approaches (anterior-lateral vs posterior) into the subacromial space. The study has ethical approval and the patient has agreed to participate. The patient will be seen again in approximately 3 months and then further questionnaires will be sent by post at 6 months and 1 year. We would be very grateful if you could send us details of the results from any physiotherapy mr/ms…….. has had in the past. Specifically we would like to know when, for how long and on how many occasions physiotherapy was attempted.

I will write to you again following the 3 month period highlighted above.

Thank you and kind regards,

Sincerely,

Mr CP Charalambous,
Consultant Orthopaedic Surgeon