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Frozen shoulder trial: At GP practice and community setting (ACCorD)

Submission date
16/12/2022

Recruitment status
No longer recruiting

Registration date
20/12/2022

Overall study status
Completed

Last Edited
28/10/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
"Frozen shoulder" is a painful condition that affects the shoulder. The joint becomes inflamed, tightening and shrinking the tissues leading to pain and stiffness. This combined pain and stiffness makes day-to-day activities difficult and stops many people from working. Most people recover, but for some symptoms continue for up to 3 years.

Current guidelines recommend frozen shoulder treatment should start with physiotherapy. If physiotherapy fails, people are then sent for further assessment at a hospital, where an injection into the shoulder may be recommended. Two types of injection can be used, a steroid to reduce inflammation, or a small amount of fluid called hydrodilation which stretches out the shrunken tissues. Both treatments can be given in the community.

We asked patients with frozen shoulder their views about treatment. They said research should focus upon prompt treatments avoiding operations where possible. Currently, there is a lot of variation in how this condition is treated. If an effective treatment can be given in the community it will mean people wait less time for treatment, with no need for a hospital visit and /or an operation; better outcomes and reduced cost to the NHS.

We want to find out which of these injections helps reduce peoples shoulder pain and stiffness, and improves the use of their arm. We will need to carry out a large study to look at which treatment offers most benefit to people. Before we do this, we need to carry out a smaller study to find out if:
- GPs and physiotherapists with expertise in frozen shoulder will agree to be involved in the research.
- People with frozen shoulder will be willing to take part in the study.
- Whether the questions we ask patients about the effect of their treatment are important and relevant to them.

Who can participate?
Adults over 18 years, with frozen shoulder.

What does the study involve?
We will ask patients with frozen shoulder in three boroughs in London and one borough in Cambridge to have either:
- a steroid injection and physiotherapy.
- an injection of steroid plus a small amount of fluid, and physiotherapy.

We will record people's progress after their treatment, and while they follow their rehabilitation. Patients and members of the public have helped us to design this study. They will continue to be involved as it is carried out. Patients will help us to communicate the findings of this study to the public in the most effective way. We will also publish our findings for colleagues.

What are the possible benefits and risks of participating?
Benefits
Both types of injection corticosteroid and hydrodilation have been shown to be safe and effective at improving pain and movement in your shoulder. Thus, these treatments may help you to return to work or your normal activities more quickly. By taking part in this study, you may be offered an injection sooner than if you did not take part in the study.
Taking part in the study may help future people with a frozen shoulder and the NHS, as we will get a better understanding of how to develop research into treatment for frozen shoulder in the future.
Shoulder x-rays are part of your routine care. If you take part in this study, you will not undergo any additional shoulder X-Rays. These procedures use ionising radiation to form images of your body and provide your doctor with clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. The chances of this happening to you are the same whether you take part in this study or not.
Risks
Both injections above are widely used throughout the NHS, and therefore we do not anticipate any increased risk to you if you take part in the study. Risks associated with injections are pain or discomfort at the injection site, extremely rarely infection, or there is a chance it may not improve your symptoms.

Where is the study run from?
Barts Health NHS Trust (UK)

When is the study starting and how long is it expected to run for?
March 2022 to March 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) Research for Patient Benefit Programme (UK).

Who is the main contact?
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Mr Livio Di Mascio (scientific), accord-bjh@qmul.ac.uk
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Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
314582

Central Portfolio Management System (CPMS)
54082

National Institute for Health and Care Research (NIHR)
203141

Study information

Scientific Title
Adhesive Capsulitis CORticosteroid and Dilation randomised controlled trial: a feasibility study in primary care

Acronym
ACCORD

Study objectives
Musculoskeletal (MSK) hubs are multi-disciplinary groups of healthcare providers, based in a community setting, with expertise in bone and joint conditions. The creation of MSK hubs nationwide provides infrastructure for the early and effective management of frozen shoulder. This potentially reduces costs to individuals and the wider NHS perhaps negating the need for a secondary care (hospital) referral.
The diagnosis of frozen shoulder is largely clinical; however, the most effective current treatment is uncertain which is reflected in the wide variation in clinical practice. Is it feasible to conduct a definitive multicentre trial in community settings of corticosteroid injection with hydrodilation (CSI & HD) compared to CSI (standard of care) for patients with frozen shoulder?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/11/2022, Bromley Research Ethics Committee (Temple Quay House, 2 The Square, Bristol Research Ethics Committee Centre, BS1 6PN, UK; +44 207 104 8118; bromley.rec@hra.nhs.uk), ref: 22/LO/0718

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Frozen shoulder

Interventions
Participants will be randomly allocated on a 1:1 ratio to CSI&HD versus CSI alone, stratified by recruiting centre. Allocation will be at the time of the injection and follow up will be continued for six months. The delivery of the treatment pathways will be piloted within the four MSK Hubs. The primary feasibility outcome will be the rate of participants enrolled into the study. Participant flow into and through the trial will be recorded as well as data completeness for the measures of clinical effectiveness and resource use using various means of data collection.

We expect to open 4 sites and obtain a recruitment rate of at least 2-4 participants per site per month. At the end of this feasibility study, the Data Safety and Management Committee will make recommendations to the Trial Steering Committee (TSC), as to whether the trial is feasible and further funding be sought to continue. The TSC will evaluate this information and make a decision based on this and other information that they require for a decision.

A member of the research team at each site will screen patients for eligibility, and when this is confirmed by a clinician, a GCP-trained member of the team will approach the patient to explain the study and gain informed consent. Participants will complete questionnaires at baseline. Participants will complete follow-up questionnaires at 6, 12 and 26 weeks after treatment. We will also collect routine hospital and community data from the electronic health records.
Data will be collected via the clinical trial IT system REDCap, hosted by Queen Mary University of London, UK. Baseline data will be directly entered onto the database by the local research team. Participants will be contacted for follow-up using email and/or SMS text message prompts and invited to complete questionnaires.

Intervention Type
Mixed

Primary outcome(s)
1. The rate of eligible participants presenting to the MSK hubs (Screening logs)
2. The proportion of eligible participants that clinicians are willing to recruit (Baseline visit 1, questionnaires)
3. The proportion of eligible participants that are randomised (Baseline visit 1/Intervention visit 2, questionnaires)
4. Adherence to the study protocol and attrition at 6 months (All visits (1-6), questionnaires)
5. Data completeness using traditional clinical reporting forms and routine data sources.

Key secondary outcome(s)
1. Upper limb function will be assessed using the Oxford Shoulder Score (OSS) (Baseline visit 2, Follow up at visit 3-6; questionnaires)
2. Quality of life will be assessed using the Euroquol (EQ-5D-5L) (Baseline visit 2, Follow up at visit 3-6; questionnaires)
3. Upper limb range of motion (Baseline visit 2, Follow up at visit 3-6; Face to face study visit measurement and also from photos of upper limb submitted by participants)
4. Resource use (Baseline visit 2, Follow up at visit 3-6; questionnaires)

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Adults with frozen shoulder, defined as:
1. Aged 18 years and older
2. Loss of passive external rotation of at least 50% compared with the contralateral side
3. Presence of symptoms for at least 4 weeks
4. Plain radiographs demonstrating the absence of glenohumeral osteoarthritis or other pathology

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
54

Key exclusion criteria
1. Recurrent ipsilateral frozen shoulder
2. Presentation following breast cancer or local radiotherapy
3. Known rotator cuff tear
4. Long-term systemic corticosteroid use, or previous ipsilateral shoulder CSI within 12 months

Date of first enrolment
14/02/2023

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
NHS Cambridgeshire and Peterborough CCG
Lockton House
Clarendon Road
Cambridge
United Kingdom
CB2 8FH

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
East Coast Community Healthcare CIC
Hamilton House
Battery Green Road
Lowestoft
United Kingdom
NR32 1DE

Sponsor information

Organisation
Barts Health NHS Trust

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			28/10/2025	No	No
HRA research summary			26/07/2023	No	No
Statistical Analysis Plan	Statistical Health Economics Analysis Plan (SHEAP) version 1.0		08/03/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes