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United Kingdom Frozen Shoulder Trial (UK FroST)

Submission date
18/07/2014

Recruitment status
No longer recruiting

Registration date
25/07/2014

Overall study status
Completed

Last Edited
04/06/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Frozen shoulder is a painful and debilitating condition causing stiffness and disability in the affected shoulder and arm. It happens when the flexible tissue surrounding the shoulder joint (capsule) becomes inflamed and thickened, resulting in contraction (tightening) of the tissue and scarring. The shoulder becomes very tight, painful and stiff. It affects around 1 in 12 men and 1 in 10 women of working age, interfering with their work, home and leisure activities. Most people eventually get better, even without treatment, and it does tends to improve and settle with time (typically taking 1 to 3 years). However, for some people it causes severe symptoms and these cases need more active treatment. Around 1 in 10 patients are referred to hospital. Hospital treatment could involve something called early structured physiotherapy (ESP), which includes education, general reassurance and advice and exercises to mobilise and stretch the tightened shoulder capsule. A steroid injection into the joint (intra-articular) can be used for pain relief. An alternative is manipulation under anaesthesia (MUA) where the shoulder is manipulated to stretch and tear the tight capsule under a general anaesthetic and therefore restoring a more normal range of movement to the shoulder. A steroid injection is again given for pain relief. Lastly, the patient can undergo keyhole surgery, again carried out under general anaesthetic, in a procedure called arthroscopic capsular release (ACR) where the tight capsule is opened up though cutting out the thickened parts using high-frequency radio waves. Steroid injections are usually avoided after this surgery to reduce the risk of infection, and alternative methods of pain relief are offered. All three of these treatments are regularly offered on the NHS, but it is not actually known which works best and at what cost. The aim of this study is to compare these three treatments for both clinical and cost effectiveness.

Who can participate?
Patients who are at least 18 years old, diagnosed with frozen shoulder and for whom secondary causes for their condition have been ruled out.

What does the study involve?
Participants are randomly allocated into one of three groups. Those in group 1 undergo ESP for 12 weeks. Those in group 2 undergo MUA. Those in group 3 undergo MUA with ACR. Participants in group 2 or 3 are then given a 12 week programme of physiotherapy, usually within 24 hours of the surgery, to reduce pain and to regain and maintain range of movement in the shoulder.

Improvements in pain, function and general wellbeing for all three groups of participants are then assessed at 3, 6 and 12 months after treatment.

What are the possible benefits and risks of participating?
There are no new treatments being tested in this study and, therefore, no new risks beyond those that are already associated with the treatments used are anticipated. All surgery involves risks, such as from general anaesthesia, bleeding, risk of deep vein thrombosis (blood clot in a major vein), damage to nerves and blood vessels in the surgical area and infection.

Where is the study run from?
James Cook University Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2014 to June 2019

Who is funding the study?
National Institute for Health Research (NIHR), Health Technology Assessment (HTA) (UK)

Who is the main contact?
Professor Amar Rangan
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Study website
http://www.york.ac.uk/healthsciences/research/trials/research/trials/ukfrost/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 13/26/01; Protocol Number V4.0 _151116

Study information

Scientific Title
Multi-centre randomised controlled trial with economic evaluation and nested qualitative study comparing early structured physiotherapy versus manipulation under anaesthesia versus arthroscopic capsular release for patients referred to secondary care with a primary frozen shoulder (Adhesive Capsulitis)

Acronym
UK FroST

Study objectives
To assess the clinical and cost effectiveness of the three treatments that are most often provided in NHS hospitals to treat primary frozen Shoulder (Early Structured Physiotherapy (ESP) versus Manipulation under Anaesthesia (MUA) versus Arthroscopic capsular release (ACR) with MUA) .

Further details can be found at: http://www.nets.nihr.ac.uk/projects/hta/132601
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0012/130701/PRO-13-26-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. North East (Newcastle & North Tyneside 2) Ethics Committee, 18/11/2014, REC Ref: 14/NE /1176
2. Substantial Amendment 1 – REC Favourable Opinion 02/02/2015
3. Substantial Amendment 2 – REC Favourable Opinion 24/05/2016
4. Substantial Amendment 3 – REC Favourable Opinion 21/12/2016

Study design
Pragmatic multi-centre randomised controlled trial with economic evaluation and nested qualitative study, with an internal pilot to check assumptions on trial recruitment and feasibility

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
Participants will be randomly allocated into one of three groups:
1. Evidence based, early structured physiotherapy (ESP) for 12 weeks (' active control') based on national clinical guidelines for management of frozen shoulder. Core elements of this are education, reassurance and advice; instruction on exercises from gentle active, gentle pendular movements in comfortable range to stretches of the tightened capsule augmented by hands-on mobilisation techniques, applied by the physiotherapist and intra-articular (into the joint) steroid injection is a core option for pain relief.
2. Manipulation under anaesthesia (MUA) without arthroscopic capsular release (ACR) within 18 weeks from randomisation. This is a day case procedure which involves controlled manipulation of the affected shoulder whilst the patient is under general anaesthesia. The manipulation stretches and tears the tight capsule restoring range of motion to the shoulder. This is not preceded by any formal surgical release of the tight structures. Steroid injection into the joint is provided for pain relief.
3. Manipulation under anaesthesia (MUA) with arthroscopic capsular release (ACR) within 18 weeks from randomisation. This typically is done as a day case procedure, where the contracted and tight shoulder capsule is released using arthroscopic (keyhole) techniques, followed by manipulation to confirm restoration of range of motion in the shoulder. Steroid injection is generally avoided following key hole surgery, as the risk of infection is increased in the presence of steroid. Alternative methods of pain relief, which are part of usual care following ACR, will be provided.

Additional procedures like posterior capsular release, subacromial decompression and supplementary steroid injections for pain control occur in a minority of patients and will be left pragmatic as a needs based intervention. Following MUA or ACR, patients will undergo a further 12-week programme of physiotherapy, normally commencing within 24 hours, with the aim of reducing pain and regaining/maintaining the mobility achieved at operation. It is expected that a steroid injection will be avoided during post procedural physiotherapy.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Oxford Shoulder Score (OSS) (12-item condition-specific questionnaire providing a total score based on the person's subjective assessment of pain and activities of daily living impairment) assessed at 3, 6 and 12 months post randomisation. Primary time point is 12 months after randomisation. OSS will also be collected at pre-treatment, as well as 6 months post-treatment

Secondary outcome measures
1. Disabilities of Arm Shoulder and Hand (DASH) - The QuickDASH will be measured at baseline, 3, 6 and 12 months.
2. Medical Outcomes Study Short Form 36-item questionnaire (MOS SF-36) to assess health related quality of life - will be collected at baseline, 3, 6 and 12 months.
3. The EQ5D-5L, generic and health economic self-complete patient-reported outcome measure - will be collected at baseline, 3, 6 and 12 months.
4. Pain measured using the Numeric Rating Scale for pain - will be collected at baseline, 3, 6 and 12 months.
5. Time to resolution- a simple subjective global question to be administered at baseline, 3, 6 and 12 months
6. Complications - All complications will be recorded at 12 months
7. Adverse events- will be collected over 12 months
8. The economic evaluation to determine the relative cost-effectiveness of three interventions for the treatment of frozen shoulder- at baseline, 3, 6 and 12 months
9. Qualitative study (Up to 45 patients and 10 to 15 health care professionals) - at 12 months

Overall study start date
01/10/2014

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Patients with frozen shoulder, including diabetics, >=18 years old
2. Passive external rotation in the affected shoulder that is <50% of the contralateral shoulder
3. Radiographs to exclude secondary causes e.g. glenohumeral arthritis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
503 patients

Total final enrolment
503

Key exclusion criteria

1. Bilateral concurrent frozen shoulders
2. Secondary to trauma or other causes
3. Trial treatments contraindicated
4. Unfit for general anaesthesia
5. Not resident to trauma catchment area of a participating trial site
6. Lack mental capacity to comply with treatment or data collection

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The James Cook University Hospital
Middlesbrough
United Kingdom
TS4 3RT

Study participating centre
30 sites
United Kingdom
-

Sponsor information

Organisation
South Tees NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We plan to disseminate trial results to key stakeholders and patients in several ways:
1. The study protocol and final reports will be submitted for publication in peer reviewed journals. We will publish various reports including the HTA monograph, journal publication, trial registry, trial website and specialist society reports. We will specifically target health professionals involved in the management of the frozen shoulder i.e., General Practitioners, Physiotherapists, Rheumatologists and Orthopaedic Surgeons.
2. Our findings will inform the deliberations of Commissioning Reference Groups and thus have access directly to commissioning instruments to drive changes of proven effectiveness.
3. Findings will be presented at key scientific meetings: the annual meeting of the British Elbow

and Shoulder Society (BESS) and the British Orthopaedic Association (BOA). Member surgeons and physiotherapists of BESS will be PIs and collaborators on this study, and their help will be sought for dissemination and adoption of findings into clinical care.
4. Findings and reports will be made available on websites of BESS and BOA to ensure this information can be accessed by consumer groups.
5. Service users will help generate patient information that is fed back directly to trial participants, for Shared Decision Making based on findings from this trial, update the entry on Wikipedia and write the Map of Medicine entry on frozen shoulder management. In this way service users will actively participate in dissemination of the conclusions of this study in a manner that is easily accessible by patients.

Intention to publish date
01/01/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ms Ada Keding, trail statistician (Ada.Keding@york.ac.uk). Ms Keding will be the point of contact for data queries.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/10/2020	07/10/2020	Yes	No
Results article	results	01/12/2020	10/12/2020	Yes	No
Results article	qualitative results	11/06/2021	14/06/2021	Yes	No
HRA research summary			28/06/2023	No	No
Results article	Implementing evidence into practice for the management of frozen shoulder: engaging with key stakeholders and evaluating barriers and facilitators using the Consolidated Framework for Implementation Research	30/05/2025	04/06/2025	Yes	No