ISRCTN71572948 https://doi.org/10.1186/ISRCTN71572948

Viscoseal Post Arthroscopic Release of Adhesive Capsulitis of the Shoulder

Submission date
10/03/2014

Recruitment status
No longer recruiting

Registration date
10/06/2014

Overall study status
Completed

Last Edited
12/04/2019

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Frozen shoulder or adhesive capsulitis is a painful and debilitating stiffening-up of the shoulder that usually happens for no apparent reason. It affects large numbers of people every year. It is costly to society, since it can cause people to be off work for extended periods of time and causes a considerable burden on health services. Generally it gets better by itself over a period of 6 to 18 months. However, in some people it can last as long as three years and leave the sufferer with a permanent loss of shoulder joint movement. When this happens, surgical manipulation of the joint or key-hole surgery may be required to restore movement to the joint. The latter is a more precise technique that has less risk of complications. Keyhole surgery to release a persistent frozen shoulder (arthroscopic capsular release) is an effective treatment. However, it does require extensive physiotherapy after the operation to stop the shoulder stiffening up again and to optimise function. This can be problematic as physiotherapy can be hampered by the pain that inevitably follows surgery. Previous research has shown that replacement of the natural joint oil, which gets washed away during the surgery, with an artificial lubricant, gives improvements in pain and function. However, it has not been established whether this is effective after key-hole surgery for frozen shoulder. This study intends to find out whether an artificial lubricant, known as Viscoseal®, can help people in their recovery after key-hole surgery for their stiff shoulder. Viscoseal® has a proven safety-record and is licensed to be used for injection into joints in Britain, Europe and the United States.

Who can participate?
Everyone aged 18 or over being placed on the waiting list for arthroscopic capsular release at Salford Royal NHS Foundation Trust Hospital can take part in the study.

What does the study involve?
Participation in the study will involve each participant being split into one of two groups. All participants are then asked to fill in a questionnaire and undergo a physical assessment before having conventional surgery for frozen shoulder. Group 1 will receive an injection of 10 millilitres (2 teaspoons) of Viscoseal® at the end of the operation and group 2 will not. All participants are then given conventional physiotherapy. They will be asked to complete questionnaires at home

in weeks 2 and 4 after surgery. They will also be asked to attend a physiotherapy out-patient department for a physical assessment by a research physiotherapist and complete questionnaires 5 weeks, 3 months and, finally, 6 months after surgery.

What are the possible benefits and risks of participating?
Benefits: We cannot say that there will be any direct benefits. Artificial joint lubricants, such as Viscoseal®, seem to be helpful in reducing pain and improving function after arthroscopy. Patients receiving the Viscoseal® may experience similar improvements in pain and function afterwards. However, we cannot guarantee that it will be effective.
Risks: It is known from previous studies that approximately 1-in-20 people experience a mild and short-lived flare-up when artificial joint lubricants, such as Viscoseal®, are injected into their joints. This can result in some degree of warmth, swelling and discomfort/ pain in the joint, which is likely to be indistinguishable from normal post-surgical inflammation. This usually responds to rest and simple anti-inflammatories, such as Ibuprofen.

Where is the study run from?
Salford Royal Hospital, UK

When is the study starting and how long is it expected to run for?
From April 2014 to April 2016

Who is funding the study?
TRB Chemedica (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2013/138DERM S

Study information

Scientific Title
Viscoseal Post Arthroscopic Release of Adhesive Capsulitis of the Shoulder: a randomised controlled pilot study

Acronym
ViPARACS

Study objectives
Aims of the proposed research
The overall aim is to investigate the principle that a single infusion of fermentative-source sodium hyaluronate (Viscoseal®) at the end of an arthroscopic capsular release procedure may be effective in helping control post-operative pain and in optimising function, leading to superior outcomes in the medium-term (4 weeks). The results of this study will be used to establish if further investigation into this is warranted and to inform the design of such studies in the future.

Primary objective
To establish whether a single injection of Viscoseal® may result in improved pain control and function in the medium term (4 weeks) for people undergoing rehabilitation post- arthroscopic capsular release for refractory adhesive capsulitis of the shoulder.

Secondary objectives
1. To assess the feasibility of this investigational approach and its acceptability to patients.
2. To give some indication of what effect sizes can be expected from this treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester East; 05/02/2014; ref: 14/NW/0012

Study design
Phase 4 pilot study single-centre randomised controlled blinded-assessor design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.citizenscientist.org.uk/research-opportunities/volunteer-patients/viscoseal-study/

Health condition(s) or problem(s) studied
Adhesive Capsulitis of the Shoulder

Interventions
All will be randomised to receive either a 10ml infusion of fermentative source sodium hyaluronate (Viscoseal®) into the joint, following evacuation of saline at the end of the operative procedure, or no infusion at all into the joint.

All will receive subcutaneous marcain 0.5% injections to incision points post-operatively, as is current practice at Salford Royal NHS Foundation Trust (SRFT).

All will undergo routine standardised physiotherapy post-operatively and will be followed up for a period of 6 months after their surgery.

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
Difference in mean Constant-Murley Score between experimental and control groups in study week five post-surgery (i.e. 32 days, +/-6 days).

This widely-used measure combines subjective ratings of pain and function with objective measures of range-of-motion and strength at the shoulder66. It is recommended by The European Society of shoulder and elbow surgery as a gold standard for the assessment of shoulder function. It consists of four subscales of pain, activities of daily living, strength and range of motion. It has been shown to be a valid, reliable and responsive instrument that correlates strongly with shoulder-specific questionnaires.

Secondary outcome measures
1. Difference in mean Constant-Murley score in weeks 13 and 25 post-operatively (i.e. 88 days, +/-13 days, and 172 days +/-13 days, respectively).
2. Difference in mean Oxford Shoulder Score pre-operatively and in weeks five (32 days, +/-6 days), 13 (88 days, +/-13 days) and 25 (172 days +/-13 days) post-operatively.
3. Difference in mean EQ-5D-3L scores pre-operatively and in weeks two (11 days, +/-6 days), five (32 days, +/-6 days), 13 (88 days, +/-13 days) and 25 (172 days +/-13 days) post-operatively.

The following outcome measures will also be taken:
1. The Disabilities of the Arm, Shoulder and Hand (DASH) Score and a measure of pain in last 24 hours (11-point numerical rating scale) will be taken pre-operatively and in weeks two (11 days, +/-6 days), four (25 days, +/-6 days), five (32 days, +/-6 days), 13 (88 days, +/-13 days) and 25 (172 days +/-13 days) post-operatively.
2. Global change in the shoulder problem, will be measured via one likert-response-type

question in weeks two (11 days, +/-6 days), four (25 days, +/-6 days), five (32 days, +/-6 days), 13 (88 days, +/-13 days) and 25 (172 days +/-13 days) post-operatively.
3. The persistence of shoulder pain symptoms, and the bothersomeness of the shoulder problem, will be measured via two likert-response-type questions pre-operatively in weeks five (32 days, +/-6 days), 13 (88 days, +/-13 days) and 25 (172 days +/-13 days) post-operatively.

The acceptability of this investigational approach to participants will be assessed by Likert-response-type and free-text-response-type questions on the occasion of the last data collection time-point 25 weeks (172 days +/-13 days) post-operatively.

Overall study start date
01/04/2014

Completion date
01/04/2016

Eligibility

Key inclusion criteria
All adults aged 18 years or over listed for arthroscopic capsular release of the shoulder, who are willing and able to give written informed consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Known or anticipated adverse reaction to artificial hyaluronans
2. Diagnosis of inflammatory arthropathy
3. Adhesive capsulitis secondary to pathology of the CNS
4. Inability to understand English to a sufficient level to be able to follow study procedures (every effort will be made to provide translators and assistive communication)
5. Inability to provide informed consent
6. Previous arthroplasty involving the target joint
7. Concurrent participation in another interventional research study

Date of first enrolment
01/04/2014

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salford Royal NHS Foundation Trust
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Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/019j78370

Funder(s)

Funder type
Industry

Funder Name
TRB Chemedica (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No