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Get them moving early: sling immobilisation following arthroscopic anterior shoulder stabilisation offers no advantage

Submission date
07/08/2017

Recruitment status
No longer recruiting

Registration date
10/08/2017

Overall study status
Completed

Last Edited
02/12/2019

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Arthroscopic shoulder stabilisation is a commonly performed operation to treat recurrent dislocation of the shoulder. There is lack of agreement about rehabilitation after arthroscopic shoulder stabilisation surgery, with most surgeons recommending immobilisation of the shoulder for three to six weeks after surgery to allow the ligaments to heal and prevent recurrence. However, one of the risks of prolonged immobilisation is residual shoulder stiffness. Advocates of early mobilisation argue that there is no apparent increased risk of recurrence and excess stiffness is avoided. It also permits early strengthening and exercises. The aim of this study is to assess the recurrence rate and shoulder function of patients after arthroscopic stabilisation of the shoulder with two different rehabilitation regimes.

Who can participate?
Patients with recurrent shoulder instability undergoing arthroscopic anterior shoulder stabilisation

What does the study involve?
On the day of surgery, participants are randomly allocated to either the early mobilisation (EM) or sling immobilisation (SI) group. The EM group is immediately allowed to move the shoulder freely as pain allows. The SI Group is kept in a sling for 6 weeks. All participants are followed up at 6 weeks, 3, 6, 12 and 24 months to assess their shoulder function and to find out whether the surgery has worked or not.

What are the possible benefits and risks of participating?
The results will show which rehabilitation programme is best for patients undergoing arthroscopic shoulder stabilisation surgery. Possible benefits of early mobilisation include reduced risk of stiffness and increased proprioception (the body's ability to sense joint movement and position). The risk of early mobilisation is the theoretical risk of the surgical repair failing.

Where is the study run from?
Woodend General Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2010 to August 2015

Who is funding the study?
NHS Grampian R&D (UK)

Who is the main contact?
Mr Sriskandarasa Senthilkumaran

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10/S0802/39

Study information

Scientific Title
Randomised control study to compare sling immobilisation with early mobilisation in patients undergoing arthroscopic anterior shoulder stabilisation surgery

Study objectives

There should be no difference in the recurrence rate and shoulder function between the sling immobilisation and early mobilisation groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Grampian R&D, 30/06/2010, ref: 10/S0802/39

Study design
Single-centre single-blind randomised control trial

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Arthroscopic anterior shoulder stabilisation for instability

Interventions
On the day of surgery, participants were randomised using sealed envelopes to either early mobilisation (EM) or sling immobilisation (SI) group. The EM group was allowed to move the shoulder freely as pain allowed immediately. The SI Group was kept in a sling for 6 weeks. All patients were followed up at 6 weeks, 3, 6, 12 and 24 months. Their function and failure of surgery were assessed using Oxford Shoulder Instability Score (OSIS).

Intervention Type
Other

Primary outcome measure
Failure of surgery, defined as subluxation or redislocation at 6 weeks, 3 months, 6 months, 12 months and 24 months

Secondary outcome measures
Shoulder instability, assessed using the Oxford Shoulder Instability Score at pre-op, 6 weeks, 3 months, 6 months, 12 months and 24 months

Overall study start date

01/08/2010

Completion date
30/08/2015

Eligibility

Key inclusion criteria
1. Patients with recurrent instability who had a Bankart lesion
2. Deemed suitable clinically and radiologically for an arthroscopic anterior shoulder stabilisation
3. No restriction on age

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 but stopped after 28

Key exclusion criteria
1. Patients with previous failed stabilisation, multi-directional instability or posterior instability
2. Patients who were unwilling to participate

Date of first enrolment
25/08/2010

Date of final enrolment
10/07/2013

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Woodend General Hospital
93 Eday Road
Aberdeen
United Kingdom
AB15 6XS

Sponsor information

Organisation
NHS Grampian R&D

Sponsor details
Aberdeen Royal Infirmary
Foresterhill
Aberdeen
Scotland
United Kingdom
AB25 2ZN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00ma0mg56

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS Grampian R&D

Results and Publications

Publication and dissemination plan
The trialists are hoping to submit the study to a journal as soon as it is registered.

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The anonymised dataset will be available for review but not for sharing with other institutions as consent was not obtained for this. The data is kept by Mr Sriskandarasa Senthilkumaran and Mr Kapil Kumar (principal investigator for the study). Consent from participants was obtained for analysis.

IPD sharing plan summary

Available on request