

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

Submission date 07/08/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/08/2017	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 02/12/2019	Condition category Surgery	☐ 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

Protocol serial number
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)

Study design

Single-centre single-blind randomised control trial

Primary study design

Interventional

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

Scotland

Study participating centre

Woodend General Hospital

93 Eday Road

Aberdeen

United Kingdom

AB15 6XS

Sponsor information**Organisation**

NHS Grampian R&D

ROR

<https://ror.org/00ma0mg56>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Results and Publications

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