

Multifactorial Approach Training for Anterior Shoulder Instability in patients undergoing arthroscopic bankart repair, a randomized controlled trial

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24933

Source

NTR

Brief title

MATASI

Health condition

Anterior Shoulder Instability

Sponsors and support

Primary sponsor: OLVG

Source(s) of monetary or material Support: OLVG

Intervention

Outcome measures

Primary outcome

To determine if multifactorial approach of aftercare is more effective in fear reduction than

the current standard of aftercare, in patients who underwent arthroscopic Bankart repair (ABR) without significant bone loss

Secondary outcome

- To assess if multifactorial approach reduces or changes specific brain activity, measured with a functional magnetic resonance imaging (fMRI) activated when anxious for potential dislocation
- To assess patient expectations before ABR
- To assess patient satisfaction before and after ABR
- To assess the psychological readiness to return to sport after 12, 24 and 48 weeks
- To modify and validate the TAMPA scale for Kinesiophobia in Shoulder Instability

Study description

Background summary

Shoulder instability is a frequently seen problem by surgeons, general practitioners, sport physicians and emergency doctors. Most often, the glenoid labrum is torn by traumatic injury causing the anterior shoulder instability. Recurrence is often used as important clinical outcome by treating physicians. However, recent literature showed that fear for (recurrent) dislocation is something that largely determines patient satisfaction and quality of life. Little is known about therapies that include treating the subsequent kinesiophobia that is caused by the shoulder instability. This produces a lack of standard multifactorial aftercare of shoulder instability surgery that includes the psychological side of the problem, such as cross-education and shoulder 'reafferentation'. This study will compare the standard aftercare after surgical treatment of shoulder instability with a newly drawn up consensus protocol by orthopaedic shoulder surgeons and shoulder physiotherapists, focussing on fear reduction.

Study objective

Multifactorial approach of aftercare, focussing on fear reduction for (recurrent) dislocation, is more effective than the current standard of aftercare for patients who underwent arthroscopic bankart repair without significant bone loss

Study design

Preoperative (1), Preoperative (2), 12wk Post-op (3), 24wk Post-op (4), 48wk Post-op (5) --> at all of these 5 time-points, patients will get a questionnaire containing questions about clinical and patient reported outcomes

Intervention

One group receives a 'standard' postoperative physiotherapy treatment and the other group receives a 'tailor-made' postoperative multifactorial physiotherapy scheme, which has been designed to reduce fear for (recurrent) dislocation

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

Patients between the age of 18 and 67, undergoing arthroscopic bankart repair (ABR) without significant bone loss at OLVG Amsterdam, Amstelland Ziekenhuis Amstelveen and/or Spaarne Gasthuis Hoofddorp/Haarlem

Exclusion criteria

Patients are excluded when they are aged under 18 or above 67 years old. Furthermore, patients undergoing other types of shoulder surgery other than arthroscopic Bankart repair will be excluded. Also patients with: absence of sulcus sign at physical examination, presence of rotator cuff rupture, bilateral component (active subluxations on contralateral side), history of soft tissue repair or bone block procedure on one of both shoulder, connective tissue disorders (e.g. Ehler-Danlos) or hyperlaxity (Beighton score >5) and/or (Current) anxiety disorders or use of anxiety suppressing drugs (e.g. anti-psychotics) will be excluded.

Study design

Design

Study type: Interventional
Intervention model: Parallel
Allocation: Randomized controlled trial
Control: Active

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-11-2021
Enrollment: 100
Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

NTR-new

Other

ID

NL9598

METC UMCU : TBA

Study results