Humeral Head Centralization Test-study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21609

Source
NTR

Brief title
HHC Test-study

Health condition

Recurrent antero-inferior shoulder instability

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: KNGF; 1500,- Euro

Intervention

Outcome measures

Primary outcome

Evaluate the glenohumeral joint translation in the instable shoulder of a patient compared with the stable shoulder of a healthy control group during external rotation of the shoulder.

Secondary outcome

Evaluate the glenohumeral joint translation in the instable shoulder of a patient compared with the stable shoulder of a healthy control group during extension of the arm.

Evaluate the inter-rater and intra-rater reliability of the ultrasound guided HHC test.
Evaluate the subjective function and stability of the affected shoulder.
Evaluate the objective stability of the affected shoulder.
Evaluate the association between the results of the apprehension test and HHC test.
Evaluate the effect of twelve weeks of motor control training on the subjective function and the joint translation during external rotation of the shoulder.

Study description

Background summary

The study is a prospective single-center trial, performed in a medical center. 25 patients with recurrent antero-inferior shoulder instability and 25 healthy control subjects will be included. The experimental group will first complete the OSIS and the WOSI whereafter they undergo a physical-and ultrasound examination of the affected shoulder. After one week the ultra-sound examination is repeated by a physical therapist and a radiologist and the patient receives a 12 week home based exercise program. After 12 weeks a final ultrasound examination is performed and the OSIS and WOSI are again completed. The control group will only receive one ultrasound examination of the shoulder.

Study objective

We hypothesize that there will be a significant difference in anterior translation of the humeral head between patients and healthy objects. Secondly we hypothesize that the inter- and intra-rater reliability of the HHC test will be fair to good. Finally we hypothesize that 12 weeks of motor control training will significantly improve the function of the shoulder.

Study design

Week 1; initial physical examination including first ultrasound examination, Week 2; second and third ultrasound examination, together with introduction to the 12 week home based exercise program. Week 14; final ultrasound examination.

Intervention

12 week home based exercise program.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet all of the following criteria: Patients 18 years or older, having had two or more involuntary re-dislocations or subluxations caused by an initial traumatic event.
The subjects of the healthy control group must meet all of the following criteria: a subject must be 18 years or older, experiencing no complaints of the shoulder.
Patients need to be able to read and write in Dutch or English language in order to complete the questionnaires, and sign informed consent.

Exclusion criteria

A potential eligible patient or subject of the healthy control group who meets any of the following criteria will be excluded from participation in this study: Patients with posterior or multidirectional instability (antero-, inferior- and posterior instability). Patients with atraumatic instability or generalized hyperlaxity (Beighton score >6 points). Patients who sustained a neurological condition or a bony lesion (As assessed on conventional radiographs) during dislocation. Patients with previous stabilizing surgery of the affected shoulder.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2021
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-01-2021
Application type:	First submission

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	ID
NTR-new	NL9202
Other	MEC-U : R19.058

Study results