Reliability of the Humeral Head Centralization Test

Published: 23-04-2020
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The aim of the current study is to provide a reliable objective parameter to indicate an anterior translation of the humeral head during movements of the arm, suggestion a motor control deficit of the rotator cuff.

Ethical review	Approved WMO
Status	Completed
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON54667

Source
ToetsingOnline

Brief title
HHC Test study.

Condition

- Tendon, ligament and cartilage disorders

Synonym
laxity of the shoulder, shoulder instability

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: Een minimale beurs van het KNGF

Intervention

Keyword: Instability, Shoulder, Ultrasound

Outcome measures

Primary outcome

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

Secondary outcome

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

Evaluate the inter rater- and intra rater reliability of the ultrasound guided HHCT.

Evaluate the subjective function and stability of the instable shoulder.

Evaluate the objective stability of the instable shoulder.

Evaluate the association between the results of the apprehension test and HHCT.

Evaluate the effect of twelve weeks of motor control training using the HHCT.

Study description

Background summary

After the initial dislocation recurrent instability has been reported in 19-46% of the patients and patient characteristics, bony- and labral lesions as well as motor control deficiency have been reported as factors related to recurrence. The choice of approach to restore stability of the glenohumeral joint is based on patient characteristics as age, gender, sport type and intensity and (bipolar) bone loss. Leaving us with a paucity concerning the

dynamic stability of the glenohumeral joint in this decision making process. The standard procedure for imaging laxity of the glenohumeral joint is static stress radiography. However several studies suggest that the use of dynamic ultrasound may also be a valid method for assessing laxity of the shoulder

Study objective

The aim of the current study is to provide a reliable objective parameter to indicate an anterior translation of the humeral head during movements of the arm, suggestion a motor control deficit of the rotator cuff.

Study design

Case-control study

Intervention

Twelve weeks exercise program consisting of stabilizing exercises.

Study burden and risks

The benefits will primarily be to society, as we will learn more about the results of the HHCT in the evaluation of treatment of shoulder instability. This group of patients who experience recurrent instability is the only population that can provide the answers to our research questions.
The burden and risk associated with returning to the Jan van Goyen Medical Center for physical examination can be considered low. Only the ultrasound assessment executed by the (second observer) radiologist and the evaluating ultrasound after twelve weeks are not part of usual care and can be seen as an extra burden.
There is no risk associated with the ultrasound assessment. These additional ultrasound assessments will be completed in 30 minutes and will be combined with the second and a final visit to the center.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients 18 years or older, having had two or more involuntary re-dislocations or re-subluxations caused by an initial traumatic event.

Exclusion criteria

Patients with posterior or multidirectional instability (anteroinferior and posterior instability). Patients with atraumatic instability or generalized hyperlaxity (Beighton score >6 points). Patients who sustained a neurological condition or a bony lesion during dislocation. Patients with previous shoulder stabilizing surgery on the affected side.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	31-05-2021
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Ultrasound scanner
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-07-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-01-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-03-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-05-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
Other	18.128
CCMO	NL69882.100.19