Quantification of shoulder dislocation by CT scanning and 3D image analysis: A pilot study

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON48986

Source
ToetsingOnline

Brief title
Quantification of shoulder dislocation

Condition

- Joint disorders

Synonym
Recurrent shoulder dislocations, shoulders that dislocate more than once

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: dislocation, pilot, Shoulder, three-dimensional

Outcome measures

Primary outcome

To quantify the degree of shoulder instability by determining the contact surface area between the glenoid and the humerus together with the translation of the humeral head during motion using three-dimensional radiographic scanning.

A separate objective is to investigate whether the BoneMRI technology can be used for accurate 3D visualization of radiodensity (CT) contrasts in the shoulder.

Secondary outcome

To link the objectively obtained parameters with measurements used in daily practise. The apprehension and relocation test will be performed to determine the correlation of the parameters with a positive test. Furthermore, cartilage thickness between glenoid and humeral head will be estimated and the volume and shape of the humerus during motion will be determined.

Study description

Background summary

Anterior shoulder dislocations are a very common problem in the general population and are often accompanied by damage to the glenohumeral capsule and glenohumeral bony structures. Prognostic factors that have been reported for recurrence after an acute first-time shoulder dislocation include age and

participation in sports, primarily collision sports and sport containing overhead activities. In young patients, these prognostic factors contribute to a reported recurrence up to 96%. Recurence contributes to additional damage to soft tissue and glenohumeral bony structures, which could lead to apprehension. Furthermore, patients are limited in daily activites and sports and (frequent) recurrences involve high social costs.

Study objective

The primary objective is to quantify the degree of shoulder instability by determining the contact surface area between the glenoid and the humerus together with the translation of the humeral head during motion using three-dimensional CT scanning. Secondly, the degree of instability will be correlated with clinical tests used in daily practice.

A separate objective is to investigate whether the BoneMRI technology can be used for accurate 3D visualization of radiodensity (CT) contrasts in the shoulder.

Study design

Cross-sectional study.

Study burden and risks

Patients will be exposed to radiation. However the exposure is minimal and qualifies as a minor risk. This study aims no direct therapeutic effects for the participants. However, the benefits are a better insight in the prognosis and adequate information for the patients. In the long term, the benefits are improved diagnostic imaging tools and a better insight in shoulder kinematics and a better diagnosis of shoulder instability.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients between the age of 18 and 50 years old that underwent recurrent anterior shoulder dislocations (n * 2). Patients need to understand the Dutch or English language to be able to sign the informed consent form.

Exclusion criteria

Patients are excluded when they have experienced a posterior dislocation, primary anterior shoulder dislocation or experienced a dislocation for any other reason than trauma. Furthermore, shoulders containing rotator cuff tears, previous surgery in the ipsi- or contralateral shoulder, a positive sulcus sign or jerk test, a beighton score of > 2, significant osteoarthritis, (pathologic) fractures or significant Hill-Sachs lesions will be excluded.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO Date:	01-10-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-01-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL66670.018.18