

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Joint disorders
<b>Study type</b>	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%. Recurrence contributes to additional damage to soft tissue and glenohumeral bony structures, which could lead to apprehension. Furthermore, patients are limited in daily activities 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