Humeral Head Centralization Test-study

Gepubliceerd: 15-01-2021 Laatst bijgewerkt: 13-12-2022

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21609

Bron
NTR

Verkorte titel
HHC Test-study

Aandoening

Recurrent antero-inferior shoulder instability

Ondersteuning

Primaire sponsor: OLVG
Overige ondersteuning: KNGF; 1500,- Euro

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

12 week home based exercise program.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	15-01-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9202
Ander register	MEC-U : R19.058

Resultaten