Does a patient-based version of the Constant-Murley score produce similar and reliable results, as compared to the original clinician-based Constant-Murley score?

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28025

Source
NTR

Brief title
CMS

Health condition

Shoulder arthroplasty
Shoulder prosthesis
Total shoulder
Totale schouder
Schouder arthroplastiek
Schouder prothese

Sponsors and support

Primary sponsor: Department of Orthopaedic Surgery, Reinier de Graaf Hospital, Delft, the Netherlands
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

The main study parameters are:

•Validity of both CM scores

oConstruct validity of both CM scores

•Reproducibility of both CM scores

oExact agreement on ordinal item scores of both CM scores between T0 and T1

oSEM for continuous item scores and total composite score of both CM scores between T0 and T1

oExact and adjacent agreement between both CM ordinal item scores at T0 and T2

oSEM for continuous item scores and total composite score between both CM scores at T0 and T2

•IRT analysis

oDiscrimination a and threshold b parameters of each item (+ ICC) and answer category (+ CRC) in both CM scores at T0 and T2

oIIF for each item in both CM scores

oSIF for both CM scores

Secondary outcome

•Smallest Detectable Change (SDC) for the continuous item scores and total composite score of both CM scores between T0 and T1

•SDC for the continuous item scores and total composite score between both CM scores at T0 and T2

•Minimal Clinically Important Difference (MCID) of both CM scores

Study description

Background summary

SUMMARY

Rationale: The Constant-Murley (CM) score is one of the most commonly used scoring systems for shoulder arthroplasty, combining assessment by the clinician (range of movement (ROM) and strength) and by the patient (pain and activities of daily living (ADL)).

A patient-based CM score was developed in the United Kingdom (UK) and tested for its reliability in a population of patients with mixed diagnoses, not including shoulder arthroplasty.
However, both scores have not been evaluated in a Dutch setting and there are varied reports regarding the reliability of the CM score, justifying further analysis alongside translation and validation of both scores in Dutch. Rating scale analysis with item response theory (IRT) modeling can evaluate the performance of items and overall scores more thoroughly.

Objective: To assess the validity, reproducibility and performance of the clinician-based and patient-based CM scores, and to determine the smallest detectable change (SDC) and minimal clinically important difference (MCID) of both CM scores in a population of patients undergoing shoulder arthroplasty.

Study design: Clinimetric study

Study population: Patients scheduled to undergo shoulder arthroplasty, aged 18 years and older.

Main study parameters/endpoints: The main study parameters are the construct validity, reproducibility (exact and adjacent agreement for ordinal scores, standard error of measurement (SEM) and smallest detectable change (SDC) for continuous scores) and performance of the separate items and overall scores assessed with IRT modeling.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: We expect no risks associated with participation, due to the nature of the study (filling out questionnaires and undergoing physical assessment in the same manner as routine care). The extra burden placed on patients will consist of two extra visits to the orthopaedic surgeon (T1 and T2) for administration of the clinician-based score, completing four extra questionnaires at baseline, completing two questionnaires at T1 and completing seven questionnaires at T2.

The MEC declared that ethical approval for this study is not necessary.

Study objective

To evaluate the validity, reproducibility and scale functioning of the Dutch clinician-based Constant-Murley (CM) score and of a Dutch patient-derived Constant-Murley score in patients with shoulder arthroplasty.

To define the smallest detectable change (SDC) and minimal important change (MIC) of both the clinician-derived and patient-derived CM score in patients with shoulder arthroplasty

Study design

T0: within 6 months pre-operatively

T1: 2 weeks after T0

T2: 6 months post-operatively

The treating orthopaedic surgeon will perform the clinician-based CM score during a clinic visit. All other questionnaires will be completed by the patients, either on paper or digital (according to patient preference)

Intervention

T0: clinician-based CM score, patient-based CM score, Oxford Shoulder Score (OSS), Simple Shoulder Test (SST), Numeric Rating Scale (NRS), EuroQoL-5D (EQ-5D)

T1: clinician-based CM score, patient-based CM score, anchorquestion

T2: clinician-based CM score, patient-based CM score, Oxford Shoulder Score (OSS), Simple Shoulder Test (SST), Numeric Rating Scale (NRS), EuroQoL-5D (EQ-5D), anchorquestion

Contacts

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Eligibility criteria

Inclusion criteria

Age 18 years or older

Scheduled to undergo shoulder arthroplasty

Able to speak and write Dutch

Willing to participate

Able to provide written informed consent

Exclusion criteria

Cognitive impairment

Difficulty with the Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-09-2016
Enrollment:	125
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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	NL5900
NTR-old	NTR6088
Other	MEC ZWH : 16-084

Study results