Clinical relevance of Clinician and Patient Reported Outcome Measures in patients with upper extremity injuries by determining Minimal Important Change (COMIC)

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The aims of this study are validation of PROMs and estimating the minimal important change (MIC) for PROMs and CROs.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22661

Bron
Nationaal Trial Register

Verkorte titel
COMIC

Aandoening

Upper extremity injury: clavicle fracture, AC luxation, shoulder dislocation, humerus fracture (proximal, shaft and distal), elbow dislocation, radius fracture (proximal, shaft, distal), ulna fracture (olecranon, shaft, distal), carpal fractures and dislocations, metacarpal fractures and dislocations, finger fractures and dislocations (proximal falanx, midfalanx, distal falanx, PIP, DIP, MCP).

Ondersteuning

Primaire sponsor: Amsterdam UMC, location VUmc
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

PROM and CRO scores to estimate MICs for PROMs and CROs.

Toelichting onderzoek

Achtergrond van het onderzoek

Upper Extremity Injuries (UEIs) form a major problem for society. UEIs have a lot of impact on physical health, but also on work, daily activities, participation, and health care costs.

In daily clinical practice, patients' rehabilitation outcome after suffered UEIs is objectified using clinical measurements and expert opinion-based outcomes (Clinician Reported Outcomes; CROs), e.g. grip strength, range of motion and radiological measurements. Other aspects such as pain, activity limitations, and restrictions in participating in daily life are not being taken into account by these traditional methods. Nowadays, Patient-Reported Outcome Measures (PROMs) are used more frequently to measure patient-based outcomes. Using PROMs can improve communication between patient and clinician, which might improve treatment and rehabilitation strategies.

However, for this aim it is important that scores and changes in scores can be clearly interpreted. A PROM might show a significant change over time, but this does not mean the patient will notice the difference and considers the change to be important. Little is known about how changes in scores should be interpreted. The smallest change that can be detected with a PROM, known as the Smallest Detectable Change (SDC), might not be relevant for the patient. A relevant change for patients is captured with Minimal Important Change (MIC). The MIC has been defined as 'the smallest change in score in the construct to be measured which patients perceive as important'.

As little is known about how changes in scores should be interpreted and what is relevant change for patients, more knowledge about the MIC is recommended. In this study we want to gain more knowledge on the psychometric properties of PROMs and interpretation of change scores in CROs and PROMs in patients following UEIs. For interpretation of the effect of treatment and rehabilitation in clinical practice a 'lean' coreset of CROs and PROs with known MICs has been proposed.

Doel van het onderzoek

The aims of this study are validation of PROMs and estimating the minimal important change

(MIC) for PROMs and CROs.

Onderzoeksopzet

Baseline measurement (reference measurement before injury), 6/7 weeks after injury, 9/10 weeks after injury, 6 months after injury and 6.5 months after injury. Completing vignettes will take place between 6 and 12 months after injury.

Onderzoeksproduct en/of interventie

No intervention in treatment. Follow up with PROMs and CROs.

Contactpersonen

Publiek

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Suus van Bruggen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with UEI (uni- or bilateral), thus; patients will be included <1 week after injury.
2. Age of 18 years or older.
(3. Extra inclusion criterium for patients suffering hand/wrist injury: unilateral injury)

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. No sufficient command of the Dutch language.
2. Patients with UE disorders; longer existing complaints (>1 week).
(3. Extra exclusion criterium for patients suffering hand/wrist injury: bilateral injury)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
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:	400
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:	12-03-2021
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	NL9337
Ander register	METC VUmc : 2020.02

Resultaten