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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22661

Source
NTR

Brief title
COMIC

Health condition

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).

Sponsors and support

Primary sponsor: Amsterdam UMC, location VUmc
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- PROM and CRO scores to validate PROMs.
- Estimating the MIC for the PROMIS UE v2.0 item bank by using the vignettes method. Development and validation of the required vignettes.

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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)

Exclusion criteria

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)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2021
Enrollment:	400
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-03-2021
Application type:	First submission

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	NL9337
Other	METC VUmc : 2020.02

Study results