LIMB-Q: Validation and field testing

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Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint injuries
Study type	Observational non invasive

Summary

ID

NL-OMON49881

Source
ToetsingOnline

Brief title
LIMB-Q validation

Condition

- Bone and joint injuries
- Bone and joint therapeutic procedures

Synonym
open fracture, severe lower extremity trauma

Research involving
Human

Sponsors and support

Primary sponsor: Duke university, dept plastic surgery
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: lower extremity, QoL, questionnaire, trauma

Outcome measures

Primary outcome

Scores on the LIMB-Q

Secondary outcome

scores on the ED-5Q and PROMIS physical functional score

Study description

Background summary

Severe lower extrem¡ty trauma can be life changing for patients. Treatment options include
immediate amputation, delayed amputation after attempts at reconstruction, and successful
limb-salvage. However, successful limb salvage often requires multiple operations, with a
high rate of complications. Alternatively, amputation results in a permanent loss of limb and
reliance on a prosthetic for ambulation. From a patient perspective, it remains unclear how
outcomes compare between reconstruction and amputation, as there is no patient-reported
outcome (PRO) instrument designed for limb threatening lower extremity injuries to collect
this data. PRO instruments are rating scales that measure concepts of interest (COI) relevant
to patients such as symptoms, appearance, function and health-related quality-of-life (QOL)
by asking patients directly. ln order to measure COI important to patients with a limbthreatening
lower extremity injury, a well-defined, valid, reliable and responsive PRO instrument is needed.
The LIMB-Q is currently being developed to meet this need.

The first two phases of LIMB-Q development have been completed at Duke using rigorous, international PRO instrument
development standards.

Study objective

The purpose of this study is to complete the third and final phase of PRO instrument
development, cross-sectional field-testing of the LIMB-Q. The field-test data will be analyzed
to identify the subsets of items for each scale that represent the best indicators of outcome
based on their performance against a standardized set of psychometric criteria. Once this is
completed, we anticipate that the LIMB-Q will provide meaningful, precise and reliable
feedback on important patient-centered outcomes with the potential for widespread use in
both clinical and research settings.

Study design

Cross-sectional

Study burden and risks

No risks are associated with this study. The main burden is the time it takes to complete these questionnaires. The outcomes of these questionnaires will be used to improve the care for these patients.

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

Had a reconstrution or amputation for a severe lower extremity trauma, in the last 20 years, aged 18 years or older, fluent in Dutch or english

Exclusion criteria

aged <18 years, not fluent in Dutch or English

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2021
Enrollment:	243
Type:	Anticipated

Ethics review

Approved WMO Date:	19-03-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL75275.078.20