

Shared goal-setting in medical decision-making: the case of lower-limb amputation in Critical Limb Ischemia.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42219

Source

ToetsingOnline

Brief title

Shared goal-setting in medical decision-making.

Condition

- Other condition
- Vascular injuries

Synonym

Severe peripheral arterial disease; severe blockage of the arteries in the lower legs

Health condition

Patienten met Kritieke Ischemie (Critical Limb Ischemia)

Research involving

Human

Sponsors and support

Primary sponsor: Gezondheids, Medische en Neuropsychologie

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Critical Limb Ischemia, Lower-limb amputation, Medical decision-making, Shared goal-setting

Outcome measures

Primary outcome

The main outcome measure will consist of a list of recurrent themes that represent the general priorities and preferences of doctors and patients regarding medical decision-making in patients with no-option CLI.

Secondary outcome

Demographic characteristics, QoL (EQ-5D-5L). The total score on the EQ-5D-5L will be used as index of quality of life.

Study description

Background summary

Medical decision-making is heavily influenced by (unexplored) assumptions from doctors towards patients and vice versa, rather than by open doctor-patient communication about (competing) doctor-patient values and priorities. This highly undesirable situation calls for an approach based on shared goal-setting (exploring a patient's values and preferences), as opposed to shared decision-making (considering only benefits and disadvantages of various treatments). However, current practice differs from this ideal situation, as no toolkit is yet available to guide doctors and patients through shared goal-setting in clinical decision-making. To be able to develop such a toolkit, this study explores the elementary components of shared goal-setting in a group of patients with Critical Limb Ischemia (CLI) facing lower-limb amputation.

Study objective

The aim of this study is to explore the elementary components in shared goal-setting in patients with no-option CLI. The transcending benefits of this study will apply to doctor-patient communication in general.

The primary objective of the study is to explore which aspects, in terms of personal values, preferences, and priorities, doctors and patients take into account when it comes to lower-limb amputation (LLA).

The secondary objective is to explore how doctors and patients experience shared goal-setting in current practice, and what they perceive as current facilitators and barriers.

Study design

This qualitative study will use semi-structured interviews to explore important themes regarding the decisional process preceding the decision whether to amputate or not. These semi-structured interviews will be conducted with 15 patients, their primary caregivers and 10 vascular surgeons. In patients and caregivers, demographics, quality of life (EQ-5D-5L) negative affect will also be assessed using validated questionnaires.

Patients treatments regimes will not be changed as a result of study participation. In total, participation in this study will take approximately 1,5 hour of an individual participant*s time (including first contact, interview and questionnaires).

Study burden and risks

No risks are involved with participation in the study. The only burden for participants is the investment of time (max. 1,5h). No direct benefits are expected to be experienced by the participants.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

A) For patients ($n \leq 15$):

- Age ≥ 18 years old
 - Being diagnosed with no-option CLI (no therapeutic possibilities left)
 - Frequently visiting the outpatient clinic to consult vascular surgeon for complaints (e.g. weekly);
- B) For primary caregivers:
- Age ≥ 18 years old
 - Having a close relationship with an included patient (e.g. partner, family member, close friend);
- C) For vascular surgeons ($n \leq 10$):
- Being responsible for the care of CLI patients at the LUMC

Exclusion criteria

For patients (A) and their primary caregivers (B):

- a diagnosis of dementia
 - or for other reasons unable to give reliable information (e.g. severe depressive symptoms, psychopathology);
- C) For vascular surgeons: No exclusion criteria.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO	
Date:	26-08-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL52309.058.15