Nutritional intake, nutritional status and physical activity level in people who have undergone a major dysvascular lower limb amputation

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The primary objective of this study is to determine the nutritional intake, nutritional status, and physical activity level at various moments post-lower limb amputation (i.e., during hospital admission for amputation, at 5 weeks post-amputation, at...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON53685

Source
ToetsingOnline

Brief title
Nutrition in the amputation population

Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
dysvascular amputation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: amputation, malnutrition, nutrition, outcomes

Outcome measures

Primary outcome

The primary outcomes are: nutritional intake, nutritional status, and physical activity level during admission for amputation, and 5 weeks, 6 months and 9 months post amputation.

Secondary outcome

The association between nutritional intake and physical activity, and nutritional status.

The association between nutritional intake, nutritional status, and physical activity, and clinical outcomes (mortality rate, wound healing, quality of life, physical function).

Study description

Background summary

People requiring a major dysvascular lower limb amputation are at high risk for adverse clinical outcomes. Undernutrition and low physical activity level may affect clinical outcomes negatively. However, little information is known about the nutritional intake, nutritional status and physical activity level in the amputation population, and their association with clinical outcomes.

Study objective

The primary objective of this study is to determine the nutritional intake,

nutritional status, and physical activity level at various moments post-lower limb amputation (i.e., during hospital admission for amputation, at 5 weeks post-amputation, at 6 months post-amputation, at 9 months post-amputation).

The other objectives are: to determine
- the association between nutritional intake and physical activity, and nutritional status.
- the association between nutritional intake, nutritional status and physical activity level, and clinical outcomes (mortality, wound healing, quality of life, physical function).

Study design

Longitudinal observational study

Study burden and risks

Patients will receive usual care and the additional study measurements are not psychological or physical demanding. Therefore, participation in this study will not lead to increased risks. The physical function measurements are lower in intensity as the usual care inpatient rehabilitation treatment. Next to this, wearing an accelerometer does not limit the participants* functioning. We will act upon case findings regarding undernutrition. If the participant is diagnosed as undernourished, the patient will be advised to consult a dietitian.
The main burden is the time investment of the participant. We will limit this as much as possible, by scheduling the measurement moments right before or after usual care visits at the rehabilitation center. Alternatively, the investigator will visit the participant at home or any other location preferred by the participant. Therefore, no extra hospital visits are required.
Furthermore, we will compensate for the time investment of the participants by providing a gift card for every study measurement.
The benefits outweigh the time burden to the participant, as the information obtained from this study will be used to improve nutritional care with the goal to improve clinical outcomes in the amputation population.

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

Undergoing or recently (i.e., within seven weeks) having undergone a major dysvascular lower limb amputation (i.e., Syme amputation or more proximal level), being 18 years or older, and being able to collaborate.

Exclusion criteria

Requiring re-amputation, current cancer diagnosis, or having a severe malabsorption disease.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-02-2023
Enrollment:	69
Type:	Actual

Ethics review

Approved WMO Date:	16-02-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-09-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT05747066
CCMO	NL81994.042.22