

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

Published: 16-02-2023

Last updated: 05-10-2024

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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Vascular therapeutic procedures
<b>Study type</b>	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**

### **Public**

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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

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