

# Critical limb ischemia: primary or secondary amputation versus intervention (bypass or PTA), impact at functional outcome.

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To assess the level of functional status of patients with critical limb ischemia after percutaneous revascularization or bypass surgery and major amputation and to identify subgroups that might benefit from primary amputation instead of...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Vascular therapeutic procedures
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON31138

### Source

ToetsingOnline

### Brief title

PRINT

### Condition

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

### Synonym

critical vascular disease, Fontaine 3 & 4

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** eigen research middelen

## Intervention

**Keyword:** amputation, critical limb ischemia, functional outcome, intervention

## Outcome measures

### Primary outcome

The main endpoint is the functional ability and QoL of patients 6 months and one year after intervention (lower limb amputation or revascularization procedure).

### Secondary outcome

Secondary endpoint is the assessment in terms of physiological and mobility parameters.

## Study description

### Background summary

The outcome of treatment of critical limb ischemia is usually expressed in physiological parameters (ankle/brachial index (ABI), patency), however, patient's level of functional outcome and health-related quality of life (QoL) are gaining more interest.

Critical limb ischemia is the end-stage of peripheral arterial disease. The primary goal of treatment is limb salvage. Much effort is put in attempts for revascularization. However, in certain cases the price paid for limb salvage is high; revascularization in some patients ends up in long hospital stay and several interventions. In these cases primary or secondary amputation is a reasonable alternative. This emphasizes the need for identification of patient groups in which amputation is preferable instead of revascularization.

### Study objective

To assess the level of functional status of patients with critical limb

ischemia after percutaneous revascularization or bypass surgery and major amputation and to identify subgroups that might benefit from primary amputation instead of revascularization.

## Study design

A prospective observational study.

## Study burden and risks

Patients are needed to attend two follow-up time points. They were asked to fill in a questionnaire and measurements (for instance ABI) will be done as part of orderly treatment. Because of its observational design there are no risks associated with participating. There are no benefits associated with participating.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

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Adults (18-64 years)  
Elderly (65 years and older)

## Inclusion criteria

Critical limb ischemia requiring therapy consisting of either a bypass or PTA or major lower limb amputation (below, through, above knee).  
Age 18 years or older.

## Exclusion criteria

Unable to fill-in self-reported questionnaires (insufficiently reading or speaking the Dutch language, cognitive disorders, etc).  
Life-expectancy less than 3 months.  
Legally incompetent adults.

## Study design

### Design

**Study type:** Observational non invasive  
**Masking:** Open (masking not used)  
**Control:** Uncontrolled  
**Primary purpose:** Diagnostic

### Recruitment

NL  
**Recruitment status:** Pending  
**Start date (anticipated):** 01-06-2007  
**Enrollment:** 200  
**Type:** Anticipated

## Ethics review

Approved WMO  
**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
CCMO	NL16964.018.07