Biomarker Expression, predicts risk of re-AMputation, impaired woundhealing and secundairy systemic cardiovascualr events, in patients with endstage peripheral atherosclerotic disease undergoing leg amputation due to advanced atherosclerotic disease. The "BEAM" study.

Published: 08-01-2012
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The objective of the study comprises the identification of (tissue) biomarkers related to the risk of re-amputaion, systemic atehrosclerotic manifestations and woundhealing in patients with critical limb ischemia by investigating tissue biopts at...

Ethical review	Not approved
Status	Will not start
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON38319

Source
ToetsingOnline

Brief title
Biomarkers and risk of re-AMputation and systemic cardiovascular events

Condition

- Skin and subcutaneous tissue therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Atherosclerosis, Critical Limb Ishemia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Amputation, Atherosclerosis, Biomarker, Personalized medicine, Wound healing

Outcome measures

Primary outcome

The study parameters have not been defined yet, a number of different proteins

will be investigated as well as histology including vessel density. These

parameters will be related to patient and follow-up data.

Follow-up parameters include:

1: re-amputation withing 3 years following primary amputation

2: woundinfection

3: duration of correct woundhealing (days following surgery, within 6 weeks

after surgery)

Secondary outcome

A: Acute other manifestations of atherosclerosis (myocardial infarction,

cerbrsl infarction and peripheral intervention)

Study description

Background summary

Patients with critilcal limb ischemia (CLI), without medical or interventional/surgical treatment options have an indication for amputation of (part) the leg. Currently, amputation of the leg it concerns has to be reoperaterated including an amputation at a higher level in a majority of patients with CLI, because of impaired woundhealing or lokal infection. Reampuations are essential in circumstances of unhealing or infected wounds, since patient may become seriously ill.
Markers related to the ideal amputation level with good healing or predicting correct woundhealing are lacking. Based on local tissue markers at the levels of amputation (biomarkers - vene, artery, muscle, subcutis) we expect ot identify biomarkers that enable risk prediction of re-amputation in patients with CLI. In the clinical setting, these markers may serve as targets determining the ideal level of amputation with good postoperative healing. This approach will contribute to a reduction of the number of re-ampuations and would predict correct woundhealing prior to the operation.
The outcome of the study will decrease hospitalization, number of operations and its related complications. The outcome will improve patients rehabilitation and reduce medical costs.
In addition the markers will be correlated with systemic cardiovascular manifestations, since patients with peripheral artery disease have an remarkable increased risk to suffer from systemic cardiovascular events.

Study objective

The objective of the study comprises the identification of (tissue) biomarkers related to the risk of re-amputaion, systemic atehrosclerotic manifestations and woundhealing in patients with critical limb ischemia by investigating tissue biopts at the level of amputation.

Study design

Observational prospective cohort study

Study burden and risks

Besides the regular outpatient clinic visits concerning regular follow-up, which is after 6 weeks and 3 months and yearly after the operation, patients recieve a questionnair prior to the operation and during follow-up they will receive half yearly a questionnaire with 5-10 questions related to the primary and secundary endpoints of the study.
Prior to surgery general bloodsamples are taken form the patients for

pre-operative screening. For this study 30 ml of additional samples will be collected. Patients should not be additionally pricked.

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

Patients between 18-99 years old with critical limb ischemia and without medical treatment options, revascularization possibilities or exercise treatment.

Exclusion criteria

Younger than 18 years old, HIV positive patients

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Not approved

Date:	08-01-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL37133.041.12