Biomarkers as predictors of wound healing after lower leg amputations in patients with severe peripheral arterial disease.

Published: 20-03-2013
Last updated: 26-04-2024

The purpose of this study is to make it possible to make a prediction of risk of amputation stump wound healing without the need for re-intervention and whether a secondary amputation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON39615

Source
ToetsingOnline

Brief title
AmpuBase

Condition

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

Synonym
critical ischemia, Intermittent claudication

Health condition

Verbeteren van kwaliteit van leven

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Amputation, angiogenesis, peripheral artery disease, wound healing

Outcome measures

Primary outcome

Those patients within 100 days are back for a re-intervention and / or a secondary amputation will be considered as bad recovering patients. Patients who have a good recovery are the patients who do not re-intervention and or secondary amputation need within 100 days. These two groups will be compared with each other and with a third group of healthy controls.

By comparing the blood and tissue from different groups biomakers wil be identified that can predict the chance of cure of an amputation wound.

Secondary outcome

.

Study description

Background summary

Peripheral arterial disease (PAD) is an important health issue. Despite current treatment options based on vascular interventions, therapeutic options for severe PAD remain limited. Critical limb ischemia (CLI) is the most severe form of PAD and many patients are not candidate for surgery and it can lead to amputation of the leg. However a delayed or a nonhealing amputation wound is a

serious additional problem and may require a secondary amputation.

Study objective

The purpose of this study is to make it possible to make a prediction of risk of amputation stump wound healing without the need for re-intervention and whether a secondary amputation.

Study design

To be able to make this prediction, in this observational study the expression patterns of pro- and anti-angiogenic factors in blood, muscle and vascular tissue from amputated limbs of PAD patients will be compared. The expression patterns in blood and tissue of PAD patients will also be compared with that of "healthy" controls (a non-PAD patient who for other reasons, for example, a trauma, undergo an amputation).
After obtaining informed consent additional blood samples will be taken for plasma and DNA samples. Subsequently, in the operating room, immediately after the performance of the amputation, biopsies will be taken from different places in the amputated leg.

Study burden and risks

.

Contacts

Public
Selecteer

Albinusdreef 2
Leiden 2300 RC
NL
Scientific
Selecteer

Albinusdreef 2
Leiden 2300 RC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients older than 18 years who undergo amputation of the lower leg

Exclusion criteria

Mental incompetence and amputation due malignancy in the leg

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-09-2014
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	20-03-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	28-04-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL41491.058.12