Vitamin c to improve wound healing after vascular surgery

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21212

Source
Nationaal Trial Register

Brief title
VITAMIN

Health condition

Vitamin c
Vitamine c
Ascorbic acid
Ascorbinezuur
Vascular surgery
Vaatchirurgie
Revascularisation
Revascularisatie
Wound healing
Wond genezing
Fontaine IIb

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: Meander Medisch Centrum

Intervention

Outcome measures

Primary outcome

Improved woundhealing in 30 days in patients with an open revascularisation of the lower extremities after treatment with
4 dosages of 2 grams ascorbic acid on 4 consecutive days. (First dosage 1 hour preoperative)

Secondary outcome

Relation between the ascorbicacid bloodlevel and the reduction in wound surface area of the primary surgical wound 4 weeks post-surgery.

Reduction in wound surface area of a secondary wound (pre-surgical existing) 4 weeks post-surgery (corrected for baseline ascorbicacid level)

Decreasing the incidence of woundinfections of the surgical wound within 30 days post-surgery(corrected for baseline ascorbicacid level)

Reduction of hospital stay (corrected for baseline ascorbicacid level)

Reduction of the number of readmissions within 30 days post-surgery(corrected for baseline ascorbicacid level)

Reduction of the number of 'all cause complications' within 30 days post-surgery (corrected for baseline ascorbicacid level)
Reduction of mortality within 30 days post-surgery (corrected for baseline ascorbicacid level)

Reduction of the time till median wound surface area healing in case the wounds in both groups are fully closed within 30 days post-surgery. (corrected for baseline ascorbicacid level)

Study description

Study objective

Intravenously administred ascorbic acid improves reduction in wound area of a vascular surgical wound of at least 30% within 4 weeks post-surgery.

Study design

Time related to surgery

Day -3/-1: Ascorbic acid level (+ secondary wound surface)

Day 0: Preoperative ascorbic acid infusion

Day 0: Surgery

Day 0: Post surgery ascorbic acid level, primary wound surface(+ secondary wound surface)

Day 1: Ascorbic acid infusion

Day 2: Ascorbic acid infusion

Day 1-2: Ascorbic acid level, primary wound surface(+ secondary wound surface)

Day 3: Ascorbic acid infusion

Day 3-4: Ascorbic acid level, primary wound surface(+ secondary wound surface)

Day 10-14: Ascorbic acid level, primary wound surface(+ secondary wound surface)

Day 26-30: Ascorbic acid level, primary wound surface(+ secondary wound surface)

Intervention

Interventiongroup receives 4 administrations of 2000mg ascorbic acid (20ml) intravenously in 4 consecutive days.

Controlgroup receives 4 administrations of NaCl 0.9% (20ml) intravenously in 4 consecutive days.

First dosage in both situaties is given 1 hour preoperative.

Contacts

Public
Meander Medisch Centrum - Klinische Farmacie

J.L.W. Pot
Maatweg 3

Amersfoort 3813TZ
The Netherlands

+31(0)338502363
Scientific
Meander Medisch Centrum - Klinische Farmacie

J.L.W. Pot
Maatweg 3

Amersfoort 3813TZ
The Netherlands
+31(0)338502363

Eligibility criteria

Inclusion criteria

Planned open arterial revascularisation on 1 or 2 legs

Age > 18 yrs

Vascular disease fontaine IIb or higher

Exclusion criteria

Age < 18yrs.

Hyperoxaluria.

Patients on dialysis.

Paroxismal nocturnal haemoglobinuria.

G6P deficiency.

Recurrent kidney stones.

Hemochromatosis.

Hemosiderosis.

Usage of deferoxamine (in the past).

Immunological disease.

Pregancy.

Bilateral surgery, other than the revascularisation.

Intolerance for study medication.

Mentally incompetent patients.

Previous participation in this study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2015
Enrollment:	40
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5290
NTR-old	NTR5397
Other	: 2014-005612-41

Study results