Does Applying More Oxygen Cure Lower Extremity Sores?

Published: 31-05-2013
Last updated: 19-03-2025

To assess the relative effectiveness of HBOT as an adjunct to standard wound care in terms of preventing amputations and improving wound healing in ischemic diabetic ulcers, and its cost-effectiveness. Secondary objectives are to assess the patients...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin vascular abnormalities
Study type	Interventional

Summary

ID

NL-OMON41563

Source
ToetsingOnline

Brief title
DAMOCLES

Condition

- Skin vascular abnormalities
- Therapeutic procedures and supportive care NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Ischemic diabetic ulcers; poorly perfused wounds

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cost effectiveness, Diabetic leg ulcer, Hyperbaric oxygen treatment, Multicenter randomised clinical trial

Outcome measures

Primary outcome

Primary endpoints are freedom of major (above ankle) amputations after 12

months, and achievement of, and time to, complete wound healing.

Secondary outcome

Secondary endpoints are pain scores, freedom of minor amputations after 12

months, TcPO2, quality of life, costs, need for vascular interventions and

safety. Moreover, markers of wound healing, coagulation and oxidative stress

will be assessed to investigate the possible working mechanisms of HBOT.

Study description

Background summary

Chronic ischemic leg ulcers in diabetic patients pose a major health care problem. Conventional treatment is complex and costly. The effectiveness of hyperbaric oxygen therapy (HBOT) as an adjunct to standard wound care is promising, although the evidence comes from small trials with heterogenous populations and interventions. Also, the cost-effectiveness of HBOT is still unclear.

Study objective

To assess the relative effectiveness of HBOT as an adjunct to standard wound care in terms of preventing amputations and improving wound healing in ischemic diabetic ulcers, and its cost-effectiveness.
Secondary objectives are to assess the patients* quality of life and the need for vascular interventions in both treatment arms.

Study design

Multicenter randomized clinical trial.

Intervention

Patients will be randomly assigned to standard (vascular surgical and local wound) care with or without HBOT. HBOT will comprise 40 sessions, 90 minutes each, at 2.5 ATA over an eight-week period.

Study burden and risks

All patients, irrespective of their allocation, will receive standard treatment consisting of endovascular or surgical revascularization (if possible) and local wound care. HBOT is a generally accepted treatment in non-healing wounds. The risks of HBOT are low. Patients in the HBOT group will receive a regular treatment regimen of 40 sessions of 90 minutes of HBOT in 8 weeks. Patients will be asked to fill in questionnaires at four time points, and to keep track of pain scores weekly during the first 8 weeks. Three visits to their outpatient surgical clinic will be scheduled, and will not deviate from usual care. The subset of 40 patients presenting at the AMC will be additionally asked to collect 24-hour urine and will be subjected to a punch biopsy of the wound edge and venous blood collection at two points in time.

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

1. Type I or II diabetes
2. Wagner 2, 3 or 4 lower extremity ulcer(s), present for at least 4 weeks
3. Leg ischemia defined as: highest ankle systolic blood pressure < 70 mmHg or toe systolic pressure < 50 mmHg or TcpO2 < 40 mmHg
4. Complete assessment of peripheral arterial lesions from the aorta to the tibial arteries with duplex ultrasonography, magnetic resonance angiography, computed tomography angiography or intra-arterial digital subtraction angiography of the ipsilateral leg
5. Age * 18 years
6. Written informed consent

Exclusion criteria

1. Previous major amputation of the leg with the index ulcer
2. COPD GOLD IV
3. Current treatment with chemotherapy, immunosuppressive drugs or systemic corticosteroids (daily 10mg or more)
4. Eind-stadium nierfalen, waarvoor dialyse nodig is
5. Metastatized malignancy.
6. Left ventricular failure with EF <20% of externe pacemaker
7. Pregnancy
8.Insufficient proficiency of Dutch language, or unability to complete the Dutch questionnaires, or not compos mentis.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2013
Enrollment:	275
Type:	Actual

Ethics review

Approved WMO Date:	31-05-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-08-2013

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-02-2014

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28958
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL44429.018.13
Other	Pending
OMON	NL-OMON28958