Does Applying More Oxygen Cure Lower Extremity Sores?

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The hypothesis is that HBOT will have additional beneficial effect in terms of wound healing and/or limb salvage over conventional (surgical or non-surgical) care for diabetic patients with leg ischaemia, with acceptable costs.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28958

Bron
NTR

Verkorte titel
DAMOCLES

Aandoening

Diabetic ischemic ulcers; leg ulcer; ischaemia; peripheral vascular disease; Diabetische ulcera; ischemie; perifeer vaatlijden

Ondersteuning

Primaire sponsor: AMC, Amsterdam
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Wound healing and limb salvage.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Chronic leg ulcers in diabetic patients pose a major health problem. Conventional treatment is complex and costly. Current evidence on the (cost-)effectiveness of hyperbaric oxygen therapy (HBOT) as an adjunct to standard wound care is equivocal because studies have been heterogenous and have included small numbers of patients. As a consequence, cost-effectiveness is still unclear.

Objectives:

The primary objective is to assess whether the effectiveness of HBOT as an adjunct to standard wound care in preventing amputations and improving wound healing in ischemic diabetic ulcers justifies its costs.

Secondary objectives are to assess the quality of life and the need for vascular interventions following both treatments.

Study design:

Multicenter randomized controlled trial.

Study population:

275 diabetic patients with ischemic leg ulcers.

Intervention:

Patients will be randomly assigned to HBOT plus usual wound care or usual wound care only. HBOT will comprise 40 sessions, 90 minutes each, over an eight week period.

Main endpoints:

Primary endpoints are freedom of major (above ankle) amputations after 12 months, and occurrence of and time to complete wound healing.
Secondary endpoints are pain scores, freedom of minor amputations after.

Doel van het onderzoek

The hypothesis is that HBOT will have additional beneficial effect in terms of wound healing and/or limb salvage over conventional (surgical or non-surgical) care for diabetic patients with leg ischaemia, with acceptable costs.

Onderzoeksopzet

Patients in both groups will be monitored for 12 months after inclusion. Throughout the 8 week treatment phase, all patients collect data about pain scores and wound healing. The questionnaires (costs, ALDS, SF-36, VASQUOL and EQ-5D) will be send to the patients home adress, accompanied by a prepaid return envelope.
Subsequently follow-up is performed by the vascular surgeon after 8 weeks, 3 months, 6 months, 12 months and after any vascular intervention. During this visits at the outpatient clinic the surgeon will collect outcome measures as mentioned.

Onderzoeksproduct en/of interventie

Patients are placed in an airtight cabin and receive 100% 2.5 ATA. A complete course of HBOT treatments involves 40 sessions, once daily, for 90 minutes.
The control group will receive wound care as usual.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Type I or II diabetes

2. Wagner 2, 3 or 4 lower extremity ulcer(s), present for at least 4 weeks. In case more than one ulcer is present, the largest will be observed as target ulcer.

3. Leg ischemia, characterized by a highest ankle systolic blood pressure < 70 mmHg, or a toe systolic pressure < 50 mmHg or a TcpO2 < 40 mmHg

4. Complete assessment of peripheral arterial lesions from the aorta to the pedal arteries with duplex ultrasonography, magnetic resonance angiography, computed tomography angiography and/or intra-arterial digital subtraction angiography of the ipsilateral leg

5. Age ≥ 18 years

6. Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous major amputation of the leg with the index ulcer

2. Chronic Obstructive Pulmonary Disease (COPD) GOLD IV

3. Current treatment with chemotherapy, immunosuppressive drugs or systemic corticosteroids (daily 10mg or more), as this interferes with normal wound healing

4. End stage renal disease requiring dialysis

5. Metastatized malignancy

6. Left ventricular failure with ejection fraction (EF) <20% or external pacemaker

7. Pregnancy

8. Insufficient proficiency of Dutch language, or unability to complete the Dutch questionnaires or not compos mentis.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2013
Aantal proefpersonen:	275
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-04-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41563
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3779
NTR-old	NTR3944
CCMO	NL44429.018.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41563

Resultaten

Samenvatting resultaten
N/A