Does Increasing Oxygen Nurture Your Symptomatic Ischemic Ulcer Sufficiently?

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HBOT will prevent amputations in patients with ischaemic DFUs

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

Samenvatting

ID

NL-OMON27651

Bron
NTR

Verkorte titel
DIONYSIUS

Aandoening

Diabetic foot ulcers, diabetes, peripheral arterial occlusive disease

Ondersteuning

Primaire sponsor: Amsterdam University Medical Centers, location AMC
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Major amputation rate (above ankle) and after 12 months of follow-up

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Diabetes is a major healthcare problem with a high incidence and morbidity. Diabetic foot ulcers (DFUs) are a major complication of diabetes, often associated with peripheral arterial occlusive disease. Currently available evidence shows HyperBaric Oxygen Therapy (HBOT) can reduce major amputation rate, but clinicians remain sceptical about the (cost-) effectiveness and feasibility of HBOT for ischaemic DFUs in clinical practice. Therefore, international vascular surgeons and HBOT-physicians feel a strong need for a sufficiently powered clinical trial to determine whether and how many HBOT-sessions may be a (cost-) effective adjunctive treatment to ischaemic DFUs.
Objective: The primary objective is to assess the (cost-) effectiveness of HBOT in addition to standard wound care and vascular surgical treatment for patients with a DFU and leg ischaemia.
Study design: An international, multi-arm multi-stage (MAMS) design is chosen to conduct an efficient randomised clinical trial. At a planned interim analysis the best performing study arm(s) will be chosen to continue.
Study population: We need up to 544 patients with a Meggitt-Wagner stage 3 or 4 DFU and proven peripheral ischaemia.
Intervention: Patients will be randomised to receive standard care (wound treatment and surgical interventions following international guidelines) with either 0, 20, 30 or at least 40 sessions of HBOT. These sessions will compromise 90-120 minutes of HBOT at a pressure of 2.2-2.5 ATA according to international standards.
Main study parameters/endpoints: The primary endpoint is major amputation rate after 12 months. Secondary objectives are amputation-free survival, wound healing, health-related quality of life and cost-effectiveness of the interventions.

Doel van het onderzoek

HBOT will prevent amputations in patients with ischaemic DFUs

Onderzoeksopzet

Patients from each (remaining) study arm will be monitored up to 36 months after randomisation. At the start of the trial, patients’ baseline characteristics will be obtained. Pain scores will be collected through first phase of the trial. Questionnaires will be completed at baseline and will be sent to the patients’ home after 3 months and 1 year. Amputation rate, ulcer recurrence, additional interventions, mortality, adverse events and costs will be monitored after 1 year and 3 years.

Onderzoeksproduct en/of interventie

Patients allocated to the intervention group will receive 20, 30 or a minimum of 40 sessions of HBOT adjunctive to standard care, as determined by the randomisation. In the group with

at least 40 treatments, the patients will receive 40 treatments. After these 40 treatments, the hyperbaric physician may decide on clinical grounds whether it seems wise to continue the HBOT treatment up to a maximum of 60 sessions. A HBOT session will take 90 to 120 minutes at 2.2-2.5 ATA. Besides the 90-120 minutes of treatment, approximately 20 minutes are required for compression and decompression. During the treatment session, the patients will breathe 100% FiO2 except for 3 blocks of 5 minutes during which atmospheric air will be administered to prevent oxygen intoxication.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Type I or II diabetes
2. One or more deep and clinically infected lower extremity ulcers, classified as Meggit-Wagner class 3 or 4, Texas class 2C, 3C, 2D or 3D, or WIfI class W>1, I>1 and fI>0), present for at least 4 weeks or after a minor amputation because of a previously existing ischaemic DFU on a toe or forefoot. In case more than one ulcer is present, the largest will be observed as target ulcer
3. Leg ischaemia, 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 intraarterial digital subtraction angiography of the ipsilateral leg
5. Patients have to be discussed in, and included after a multidisciplinary consultation.

6. Adults
7. Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Chronic Obstructive Pulmonary Disease (COPD) GOLD IV
2. Treatment with chemotherapy, immunosuppressive drugs or systemic corticosteroids within last 3 months, as this interferes with normal wound healing
3. End-stage renal disease requiring dialysis
4. Metastasized malignancy
5. Left ventricular failure with ejection fraction (EF) <20% or external pacemaker
6. Recent thoracic surgery or middle ear surgery
7. Severe epilepsy
8. Uncontrollable high fever
9. Pregnancy
10. Insufficient proficiency of local language/English, or inability to complete the questionnaires

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	544
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-12-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52592
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9152
CCMO	NL72855.018.20
OMON	NL-OMON52592

Resultaten