Hyperbaric Oxygen Therapy for Pyoderma gangrenosum As a New Treatment Strategy

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To investigate the therapeutic efficacy and feasibility of hyperbaric oxygen (HBO) in addition to standard wound care in patients with pyoderma gangrenosum wounds.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Immune disorders NEC
Study type	Interventional

Summary

ID

NL-OMON53965

Source
ToetsingOnline

Brief title
HOT PANTS

Condition

- Immune disorders NEC
- Skin and subcutaneous tissue disorders NEC

Synonym
Pyoderma gangrenosum; dermatitis ulcerosa

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hyperbaric Oxygen Therapy, Pyderma gangrenosum

Outcome measures

Primary outcome

To assess the clinical effectiveness in wound healing time (full re-epithelialization) and to confirm the hypothesis the feasibility and possible efficacy of hyperbaric oxygen therapy in patients with pyoderma gangrenosum refractory to standard prednisone therapy.

Secondary outcome

- Changes in markers of inflammation, mRNA expression in micro-biopsies in wound edges.

- Alterations in mitochondrial O2 levels

- The number of activated neutrophils in peripheral venous blood.

- To assess the effect of HBOT on Pain reduction (NRS score).

- To assess the effect of HBOT on Health Related-Quality of Life (WOUND-Q).

- To assess the prevalence of recurrence of PG in patients treated with and without adjuvant HBOT.

Study description

Background summary

Pyoderma gangrenosum (PG) is a rare, uncommon auto-inflammatory neutrophilic dermatosis characterized by a spectrum of clinical presentations with variable courses. Diagnosis and management are challenging in PG, and treatment is directed towards reducing the associated inflammation that leads to ulceration including systemic prednisone and anti-TNF alpha therapy. Positive effects of

hyperbaric oxygen (HBO) therapy have been proposed in small case series.

Study objective

To investigate the therapeutic efficacy and feasibility of hyperbaric oxygen (HBO) in addition to standard wound care in patients with pyoderma gangrenosum wounds.

Study design

Prospective cohort study with long-term (one year) follow-up.

Intervention

30 sessions of HBO therapy at 2.4-2.5 atmosphere absolute in addition to treatment conform clinical practice. Controls will be treated according to clinical practice.

Study burden and risks

Burden: All 15 patients need to undergo 30 sessions of hyperbaric oxygen treatment (6 weeks, 5 times a week, 110 minutes per session) at 2.4 to 2.5 atmosphere absolute.The risks of HBOT are regarded as low. Extensive medical intakes by a hyperbaric physician will exclude substantial risks for patients during hyperbaric exposure.
Other study procedures such as non-invasive wound measurement is a part of standard clinical practice in pyoderma patients, only specific wound related laboratory measurements (non-invasive mitochondria measurement, micro-invasive biopsy of wound edges and neutrophil counts in venous blood) are extra for this study and have a low risk of complications. There is no additional burden involving the patient reported outcomes (questionnaires: pain score and WOUND-Q).

Benefits: patients could potentially benefit from this treatment in terms of faster wound healing time, improved health and quality of life and pain reduction.

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

• - Confirmed consensus on the diagnosis pyoderma gangrenosum by referring specialist, principal and coordinating investigator (dermatologist, clinical immunologist or rheumatologist based on PARACELSUS and Delphi score).
- Unsatisfactory response after six weeks of combined standard wound care and systemic prednisone and/or other anti-inflammatory therapy.
- Fit for hyperbaric oxygen therapy as assessed by the hyperbaric physician.
- Age >=18 years at baseline
- All genders
- Able and willing to give written informed consent and to comply with the study requirements.

Exclusion criteria

• Language barrier
• Unable to give informed consent
- Pregnancy

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-03-2023
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	(Hyperbaric) Oxygen
Generic name:	(Hyperbaric) Oxygen
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	13-07-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	29-08-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	21-04-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-05-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2021-006013-11-NL
CCMO	NL80793.078.22