The effect of Hypbaric oxygen therapy in the treatment of hidradenitis suppurativa: a randomised controlled trial

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To find a suitable treatment option for the 25% of HS patients who are therapy-resistant. Additionally, we expect a faster healing time of the wounds, meaning that even if patients respond to current treatment, HBOT may improve their quality of life…

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON55331

Source
ToetsingOnline

Brief title
HBOT in HS

Condition

- Skin and subcutaneous tissue disorders NEC

Synonym
acne inversa, fox-den disease

Research involving
Human

Sponsors and support

Primary sponsor: Gelre Ziekenhuizen

Source(s) of monetary or material Support: Wetenschapsfonds Gelre Ziekenhuizen,Da Vinci Klinieken

Intervention

Keyword: Hidradenitis suppurativa, hyperbaric oxygen therapy, wound healing

Outcome measures

Primary outcome

Do HBOT improve wound healing in HS lesions?

Outcome parameters: Hurley staging, Hidradenitis Suppurativa clinical response

score, wound size reduction

Secondary outcome

Does HBOT improve the quality of life in HS patients?

Outcome parameter: dermatology quality of life index

Study description

Background summary

Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease, characterised by deep abscesses and fistulae in the axillary, groin and genital regions. Often the patients are young women who are overweight and who smoke. The treatment is usually requires a multidisciplinary approach. Firstly, conservative treatment is preferred, including lifestyle advice and encouragement to quit smoking and to lose weight. Medication is the next form of treatment, such as antibiotics, anti-TNF medications and local creams. If that is insufficient, surgical drainage or excision may be required. In some cases radical resection and skin grafts may be required.

In approximately 75% of patients one, or a combination of the above mentioned treatments, will provide sufficient relief. However, for the remaining 25% of patients, there is a chronic skin disease, which has a big impact on the psychosocial functioning of the patient. Perhaps hyperbaric oxygen therapy (HBOT) is an appropriate treatment for patients who do not respond to the current treatment options. HBOT has been described in the literature as a treatment method for chronic wounds such as diabetic foot ulcers and chronic

lesions following late radiation injuries.

The number of adequately performed randomised clinical trials is low. Various case series and case reports show promising results in the healing of chronic wounds which do not respond to regular treatment methods and where ischemia in the wound area plays a role. In the case that there is local ischemia or hypoxia, the wound healing process gets stuck in the inflammatory phase and therefore no wound healing can take place. Additionally, a chronic wound will be colonised by bacteria, which also has a negative effect on the healing process.

HBOT has few side effects. Above all, the expectation is that the quality of life will be improved by a shorter treatment time. Until now, there has only been one RCT investigating the effects of HBOT in HS patients. In this trial there were 43 patients included, where all patients received antibiotics alongside the HBOT intervention. All the patients who were treated with HBOT had a clinically relevant improved healing rate.

Study objective

To find a suitable treatment option for the 25% of HS patients who are therapy-resistant. Additionally, we expect a faster healing time of the wounds, meaning that even if patients respond to current treatment, HBOT may improve their quality of life and reduce the duration of chronic wounds.

Study design

Prospective randomised controlled clinical trial following the intention to treat protocol with 30 patients per study arm (allowing for an estimated loss to follow up of 4 patients per arm)

Intervention

In combination with standard care (lifestyle advice, medication, potential operation as seen suitable by the treating doctor), 20 sessions of 2 hours HBOT (5 days per week for 4 weeks). Any operations will be determined by the patients treating doctor.

Study burden and risks

There have been a few cases described where patients undergoing HBOT experienced adverse events such as otitis media or pneumothorax. Considering that patients with a serious lung disease have been excluded, we expect the risk to be small.

This trial demands a big time burden for the patients in the HBOT group. On the

other hand, we expect a quicker reduction in disease severity, which will ultimately lead to less time in the hospital and less operations.

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

Hurley stage IIB,IIc or III, men and women aged 18-60

Exclusion criteria

History of pneumothorax, lung emphysema
Current otitis media

Inability to equalise ear pressure

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	08-05-2022
Enrollment:	100
Type:	Anticipated

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:	17-12-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	31-03-2021
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2019-002072-14-NL
CCMO	NL70172.018.20