Treatment of skin severity in Ichthyosis with hyperbaric oxygen therapy

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28824

Source NTR

Brief title HOT-TreSSI

Health condition

Ichtyosis, bacterial skin infection, fungal skin infection

Sponsors and support

Primary sponsor: None **Source(s) of monetary or material Support:** Vereniging voor Ichthyosis Netwerken

Intervention

Outcome measures

Primary outcome

Feasability of the intervention in this patient group; changes in PROMs (Patients Global Assessment, pain, desquamation, sleep and pruritus scores, medication usage and Quality of life using skindex-29); changes in doctors reported outcomes (objective skin scoring with IGA-NS, TLSS NS and BSA); assessing the safety and feasibility of HBO in patients with ichthyosis

Secondary outcome

Changes in laboratory findings; Changes in histologic findings in skin biopsies reviewed by a pathologist; Side effects; Regret analysis

Study description

Background summary

Ichthyosis is a group of genetically and phenotypically heterogeneous skin disorders characterized by dry, scaling skin that may be thickened or very thin and can be associated with additional cutaneous symptoms. The majority of ichthyoses are inherited. For example, Netherton syndrome (NS) is a rare autosomal recessive form of severe ichthyosis. Patients with severe ichthyoses (for example NS) suffer from chronic inflammation and skin infections because of the constant skin barrier impairment. These profound comorbidities in ichthyosis patients have a major impact on the quality of life, for which currently only symptomatic treatment is available This points out the need for alternative treatment options. Hyperbaric oxygen therapy (HBOT) has been proposed for this because of anti-inflammatory and immune-modulating effects. The therapy has been used for years in wound healing and postradiation fibrosis, and more importantly, can be applied for chronic osteomyelitis and anaerobic infections. It is generally considered safe and may help treat these frequent infections and associated symptoms. The current study is meant as pilot study to assess feasability of the treatment for this disease.

Study objective

HBOT can be used to treat the frequent superficial skin infections of patients with ichtyosis and might improve disease-associated symptoms.

Study design

0, 4, 8, 20, 44 weeks

Intervention

Hyperbaric oxygen therapy

Contacts

Public

Amsterdam University Medical Center

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Eligibility criteria

Inclusion criteria

Confirmed diagnosis of ichtyosis, >18 years old, can understand Dutch or English language

Exclusion criteria

Unfit for hyperbaric oxygen therapy (as determined by hyperbaric physician), unable to give informed consent, language barrier, actively smoking or stopped smoking <3 months ago

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2021
Enrollment:	6

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Type:

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Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description N/A

Ethics review

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Positive opinion	
Date:	03-09-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55363 Bron: ToetsingOnline Titel:

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

No registrations found.

In other registers

Register NTR-new CCMO OMON ID NL7998 NL69300.018.20 NL-OMON55363

Study results

Summary results

N/A