Treatment of skin severity in Ichthyosis with hyperbaric oxygen therapy

Gepubliceerd: 03-09-2019 Laatst bijgewerkt: 19-03-2025

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

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

Samenvatting

ID

NL-OMON28824

Bron
Nationaal Trial Register

Verkorte titel
HOT-TreSSI

Aandoening

Ichtyosis, bacterial skin infection, fungal skin infection

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: Vereniging voor Ichthyosis Netwerken

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

0, 4, 8, 20, 44 weeks

Onderzoeksproduct en/of interventie

Hyperbaric oxygen therapy

Contactpersonen

Publiek

Amsterdam University Medical Center
Rutger Lalieu

+31654347959

Wetenschappelijk

Amsterdam University Medical Center
Rutger Lalieu

+31654347959

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2021

Aantal proefpersonen: 6

Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N/A

Ethische beoordeling

Positief advies
Datum: 03-09-2019

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55363
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A