Hyperbaric Oxygen Therapy for the Treatment of Perianal fistulas In Crohn’s disease

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23412

Source
NTR

Brief title
HOT-TOPIC trial

Health condition

Crohn's disease, Morbus Crohn, perianal fistula(s), fistulising Crohn's disease, inflammatory bowel disease, IBD.
Ziekte van Crohn, perianale fistels, fistelende ziekte van Crohn, inflammatoire darmziekte.

Sponsors and support

Primary sponsor: Academic Medical Centre, Amsterdam
Source(s) of monetary or material Support: Academic Medical Centre, Amsterdam

Intervention

Outcome measures

Primary outcome

Co-primary parameters:

- Perianal disease activity index (PDAI) as assessed by the primary physician (gastroenterologist or surgeon) and patient.

- MRI-imaging, assessed by an independent radiologist using the (modified) van Assche score.

Secondary outcome

- Fistula drainage assessment (FDA) performed by the primary physician.

- Laboratory findings (CRP and fecal calprotectin).

- Patient reported outcomes (PROs: IBDQ and EQ-5D-5L).

- (Changes in) use of concomitant medication, among which the number of courses of antibiotics, within the course of the study (60 weeks).

- Re-interventions within the course of the study (60 weeks).

- Complications during HBO.

Study description

Background summary

Patients will be recruited through the outpatient fistula clinic in the AMC. Patients that are willing to participate will be asked whether they want to receive hyperbaric oxygen therapy or if they want to serve as a controlgroup, continuing to receive standard care. If they choose to undergo hyperbaric oxygen therapy (n = 20) treatment will start directly at the beginning of the study and will last for 8 weeks (= 40 sessions). After 30 sessions the seton will be removed. Patients will be followed until 1 year after treatment, using the earlier mentioned parameters/outcomes. The control group will be followed for the same period of time, but without MRI or labwork. If patients refuse hyperbaric oxygen therapy or participation, they will be asked for their reasons for refusal (in regards to feasibility).

Study objective

Hyperbaric Oxygen Therapy is an effective and feasible therapy option for therapy-refractory patients with perianal fistulas in Crohn's disease.

Study design

HBO therapy will start directly a the beginning of the study, week 0-8. Timepoints for HBO group:

PDAI: baseline, week 16, 34 and 60.

MRI: baseline, week 16 and 60.

FDA: baseline, week 16, 34 and 60.

Labwork: baseline, week 16, 34 and 60.

PROs: baseline, week 16, 34 and 60.

The parameters and timepoints for the control group are:

PDAI: baseline, week 16, 34 and 60.

FDA: baseline, week 16, 34 and 60.

PROs: baseline, week 16, 34 and 60.

Intervention

Hyperbaric oxygen (HBO) group: a total of 40 sessions of HBO, 30 before the removal of the seton and 10 after. One session consists of a total of 80 minutes of 100% oxygen with 5-minute airbreaks, with a total session time of 110 minutes. The pressure that will be used is 2.4-2.5 atmosphere absolute.

Control group: standard care (medical or surgical) as deemed necessary by the primary physician (gastroenterologist and/or surgeon).

Contacts

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Eligibility criteria

Inclusion criteria

- Confirmed diagnosis Crohn’s disease

- Actively draining high perianal fistula (>1/3 through external sphincter), regardless of number

- Failure of treatment with standard care (medical and/or surgical) > 6 months or intolerance to standard treatment

- Standard care treatment regimen has been stable for at least six weeks

- > 18 years

- Written informed consent

Exclusion criteria

- Unfit for hyperbaric oxygen therapy as assessed by the hyperbaric physician

- Language barrier

- Unable to give informed consent

- Patients without a seton

- Patients with a seton in situ > 12 months

- Patients with anal stricture

- Patients with rectovaginal fistulas

- Patients with stoma

- Patients with deep ulcers in the rectum

- Presence of fluid collection/abscess that needs to be surgically drained

- Prior surgical procedure in the preceding 3 months

- Patients with a contraindication to undergo MRI (claustrophobia, intravenous contrast allergy)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2017
Enrollment:	20
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	06-09-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47818
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6489
NTR-old	NTR6676
CCMO	NL60640.018.17
OMON	NL-OMON47818

Study results

Summary results
N.A.