Hyperbaric Oxygen Therapy for the treatment of RectoVaginal fistulas in Crohn's Disease.

No registrations found.

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

Summary

ID

NL-OMON24386

Source
NTR

Brief title
HOT-REVA trial

Health condition

Crohn's disease, rectovaginal fistulas, inflammatory bowel disease.

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Amsterdam UMC

Intervention

Outcome measures

Primary outcome

Clinical closure of fistula, defined as cessation of complaints, i.e. passage of feces or flatus per vagina, or closure of the external orifice if visible at baseline.

Secondary outcome

- Response/remission of co-existing perianal fistulas measured by PDAI (perianal disease activity index) and FDA (fistula drainage assessment)

- Patient reported outcomes (PROs: EQ-5D-5L, IBDQ, FIQL, FSFI, decision regret scale)

- (Changes in) use of concomitant medication within the course of the study (58 weeks)

- Re-interventions for both luminal as well as perianal disease within the course of the study (58 weeks)

- Percentages of and reasons for refusal to participate (in) or finish the study, if available

- Adverse events during HBO and during follow-up

Study description

Background summary

The goal of this study is to assess the use of hyperbaric oxygen therapy for rectovaginal fistulas in Crohn's Disease. 10 patients will be recruited through the outpatient fistula clinic in the AMC. Treatment will start directly at the beginning of the study and will last for 6 weeks (= 43 sessions). Patients will be followed until 1 year after treatment, using the earlier mentioned parameters/outcomes.

Study objective

Based on earlier research in IBD patients in general and perianal fistulas in specific, hyperbaric oxygen therapy might be an effective (adjunctive) treatment for rectovaginal fistulas in Crohn's disease.

Study design

Baseline and week 10, 18, 32 and 58 (i.e. 1, 3 6 and 12 months after 6 weeks = 30 sessions of HBO).

Intervention

30 sessions of hyperbaric oxygen therapy, consisting 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.

Contacts

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Eligibility criteria

Inclusion criteria

- Confirmed diagnosis Crohn’s disease as specified in the guidelines by the European Crohn’s and Colitis Organisation 17

- One or more rectovaginal fistula(s), defined as:

o Patient history typical for rectovaginal fistula (complaints of passage of flatus or stool per vagina), and/or

o Fistula orifice in mucosa of vagina visible during physical examination

- Current treatment regimen has been stable for at least six weeks (i.e. no starting of antibiotics, surgical intervention other than seton placement or removal, addition of immunosuppressants or dosage changes of biologicals)

- > 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

- Vaginal fistula other than rectovaginal, such as enterovaginal fistulas

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2018
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-11-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46287
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6755
NTR-old	NTR7624
CCMO	NL67017.018.18
OMON	NL-OMON46287

Study results