HYPerbaric OXygen therapy for benign anastomotIC esophageal strictures: a pilot study

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The overall objective of this pilot study is to evaluate the effect of HBOT on recurrent and refractory esophageal anastomotic strictures.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON40612

Source
ToetsingOnline

Brief title
HYPOXIC-study

Condition

- Gastrointestinal stenosis and obstruction

Synonym
anastomotic stenosis, benign esophageal stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: benign esophageal stricture, hyperbaric oxygen therapy

Outcome measures

Primary outcome

- To assess the effect of HBOT mean dysphagia free period

Secondary outcome

- To assess the effect of HBOT on;

- number of reinterventions for recurrent dysphagia

-number of patients who are dysphagia free for 6 months

- quality of life (QLQ-C30 + OES 18)

Study description

Background summary

The ideal treatment modality for recurrent and refractory esophageal anastomotic strictures has not yet been established. Since ischemia is found to be an important risk factor for the development of strictures, reversing tissue hypoxia might have a role in the treatment of recurrent and refractory anastomotic strictures. Tissue hypoxia can be reversed by using hyperbaric oxygen therapy (HBOT). Studies on the effect of HBOT on anastomotic strictures in humans have not yet been performed. However, two studies in rats with colonic anastomoses showed that ischemia impairs anastomotic healing and that adequate tissue oxygenation is the main factor for wound and anastomotic healing.

Study objective

The overall objective of this pilot study is to evaluate the effect of HBOT on recurrent and refractory esophageal anastomotic strictures.

Study design

Prospective, single-arm, pilot study in 10 patients

Intervention

Hyperbaric Oxygen Therapy

Study burden and risks

The burden of participation in this study is significant and comprises HBOT for 6 weeks, 5/days a week for 110 minutes per session. However, the included patients are those patients already suffering from dysphagia complaints for a long time and are treated with Savary dilations for a long period on short, regular intervals. The potential benefit of participation in this study is an increased dysphagia free interval and hopefully no recurrence of dysphagia at all. In case of an increased dysphagia free interval, the interval between Savary dilations will increase and less dilations sessions will be necessary. The risk of participation is low, as the potential side effects of HBOT are mild and reversible.

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

- Benign esophageal anastomotic stricture; defined as a stenosis at the esophagogastric anastomosis causing clinically significant dysphagia.
- Clinically significant dysphagia; defined as grade 2 or worse on the Ogilvie scale
- First presentation of dysphagia due to the stricture within 6 months after surgery
- Recurrent or refractory stricture:
> 5 previous dilation sessions for this indication
- Last dilation < 1 week before the start of HBOT
- Informed Consent

Exclusion criteria

- Known or strongly suspected esophageal motility disorder
- Known or strongly suspected malignant stricture
- Non-anastomotic esophageal stricture
- Contra indication for HBOT:
- Untreated pneumothorax
- Restrictive treated pneumothorax (without thoraxdrain)
- Severe respiratory diseases (COPD or pulmonary emphysema)
- Active infection of the upper airways
- Recent surgery of the middle ear
- Recent thoracic surgery
- Uncontrolled high fever
- Epilepsy
- Treatment with pulmonary toxic medication (bleomycine, doxorubicin, adriamycin, amiodaron,
furadantine)
- Previous treatment with bleomycine with pulmonary toxic reaction
- Known pregnancy or premenopausal woman that are not surgically sterile or taking oral contraceptives

Study design

Design

Study phase: 3

Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-11-2013
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Conoxia
Generic name:	Oxygen medicinal liquid
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	12-03-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-09-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-02-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-04-2015
Application type:	Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2013-000603-16-NL
CCMO	NL43628.041.13