Hyperbaric OXygen therapy for ACute Acoustic Trauma

No registrations found.

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

Summary

ID

NL-OMON21793

Source
Nationaal Trial Register

Brief title
HOXACAT

Health condition

Acute Acoustic Trauma

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC
Source(s) of monetary or material Support: Stichting Ziektekostenverzekering Krijgsmacht

Intervention

Outcome measures

Primary outcome

The main study endpoint is the absolute average hearing gain on all affected frequencies at three months follow-up. Affected is defined as the frequencies that have ≥ 20 dB hearing loss on pre-treatment audiogram compared with:
1) a previous audiogram of the affected ear that was produced within a year prior to the

current visit; or
2) the unaffected ear; or
In case both ears are affected, affected frequencies will be defined as those frequencies that do not comply with the Ministry of Defence hearing standard (maximum accepted hearing impairment of 20 dB at frequencies lower than 3 kHz and maximal hearing impairment of 30 dB at frequencies of 3 kHz or higher).

Secondary outcome

Additional audiometric outcomes include relative hearing gains on all affected frequencies, word recognition (hearing level at which 100% of words can be discriminated) and word recognition (% of words recognized) at 80 dB in case 100% is not yet reached at that level.

Study description

Background summary

Acute acoustic trauma (AAT) is a sensorineural hearing impairment due to exposure of the hearing organ to acoustic overstimulation by intense impulse noise, which can cause permanent hearing loss. This study is a randomized, non-blinded superiority trial comparing hyperbaric oxygen therapy (HBOT) twice daily for five days with HBOT once daily for ten days (current treatment protocol in the military). In both treatment arms patients will receive oral corticosteroid treatment. Patients with AAT will be recruited at the Department of Otolaryngology, Central Military Hospital (CMH). Here, they will be offered to receive HBOT with corticosteroids, subsequently they will be asked whether they want to participate in the trial. Patients will be randomized in two-treatment arms which are HBOT 5 days or HBOT 10 days, with 1:1 allocation. They will receive a standard audiogram with speach recognition tests at the CMH 24-72h after AAT and one month after AAT.

Study objective

It is expected that HBOT twice daily for five days is more effective than HBOT once daily for ten days.

Study design

Pre-treatment audiometry will be measured 24-72 hours after AAT as baseline measurement. HBOT will be started as soon as possible after inclusion.
Follow-up HBOT sessions will be performed on consecutive days, including weekends.
Post-treatment audiometry will be measured 30 days (+/- 3 days) after the final HBOT session.

Intervention

HBOT twice daily for 5 days + corticosteroids vs HBOT once daily for 10 days + corticosteroids.

Contacts

Public
Amsterdam UMC, location AMC
Robert Weenink

+31621827463
Scientific
Amsterdam UMC, location AMC
Robert Weenink

+31621827463

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Diagnosed with AAT based on audiometry after high impact noise-exposure at the Department of Otorhinolaryngology, Central Military Hospital.
- First visit to the Department of Otolaryngology between 24 and 72 hours after the acoustic trauma.
- Age ≥ 18 years old.
- Minimum hearing loss: ≥ 30 dB on one tested frequency, or ≥ 25 dB on two tested frequencies, or ≥ 20 dB on three tested frequencies. When a previous audiogram is known, then the additional hearing loss due to AAT should be minimal the above.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded:
- Subject does not speak fluent Dutch
- History of idiopathic sudden sensorineural loss.
- History of radiation therapy in the head and neck region.
- Previous acute acoustic trauma (before current trauma) with objectified hearing loss.
- Current or previous use of ototoxic drugs with objectified complaints before the current visit.

- Known presence or history of vestibular schwannoma or cholesteatoma.
- Current otitis media.
- Epilepsy.
- Known presence of untreated pneumothorax.
- Known Chronic Obstructive Pulmonary Disease Gold IV grade or other pulmonary disease with severe air trapping.
- Known severely reduced cardiac ejection fraction.
- Implanted device that is not proven to be compatible with HBOT.
- Claustrophobia that interferes with taking place in hyperbaric chamber.
- Inability to equalize middle ears using Valsalva manoeuvre. (If so, patients are offered tympanostomy tubes if they wish to participate before being excluded.)
- Current pregnancy.
- Use of adriamycin, bleomycin, cisplatin, or doxorubicin in previous six months.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2022
Enrollment:	84
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	01-12-2020
Application type:	First submission

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
NTR-new	NL9123
Other	METC AMC : 76096

Study results