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Efficacy of balloon Eustachian tuboplasty

Submission date
21/11/2017

Recruitment status
No longer recruiting

Registration date
23/11/2017

Overall study status
Completed

Last Edited
14/11/2022

Condition category
Ear, Nose and Throat

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English Summary
Background and study aims
Secretory otitis media is an ear condition where fluid accumulates behind the eardrum and remains there after an ear infection or blockage of the eustachian tube that drains fluid from the ears. Balloon Eustachian tuboplasty (BET) is a potential treatment option where a balloon is inserted into the Eustachian tube, inflated, then withdrawn. About 70-80% of adult patients seem to benefit from BET, at least briefly. Strong evidence of its long-term effectiveness is required. The aim of this study is to assess the effectiveness of BET in patients withlong-term Eustachian tube dysfunction.

Who can participate?
Patients with persistent secretory otitis media or Eustachian tube dysfunction

What does the study involve?
Participants are randomly allocated to be treated with either BET or sham surgery under local anaesthetic. Ear examinations are carried out 3 and 12 months after the operation.

What are the possible benefits and risks of participating?
There may be no direct benefit for the patient but the information revealed from this study will help improve the treatment of people with ETD. There are no known severe risks associated with BET.

Where is the study run from?
1. Helsinki University Hospital (Finland)
2. Tampere University Hospital (Finland)
3. Turku University Central Hospital (Finland)

When is the study starting and how long is it expected to run for?
January 2017 to May 2022

Who is funding the study?
1. State funding for university level health research (Finland)
2. Research Foundation for ENT Disorders (Finland)

Who is the main contact?
Dr Saku Sinkkonen

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
§97/2017

Study information

Scientific Title
Efficacy of balloon Eustachian tuboplasty - prospective, blinded and placebo-controlled multi-centre study

Acronym
EBET

Study hypothesis
Balloon Eustachian tuboplasty (BET) offers benefit to patients with persistent secretory otitis media, severe symptoms of Eustachian tube dysfunction (ETD) or baro-challenged ETD.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Tampere University Hospital Ethics Committee, 02/05/2017, ref: R17040

Study design
Prospective blinded placebo-controlled multi-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Condition
Persistent secretory otitis media, severe symptoms of ETD or baro-challenged ETD

Interventions
Parallel-group randomisation is made after local anaesthesia induction before the operation. Patients are treated with either BET or sham surgery under local anaesthesia. The patients are blinded to the procedure. Postoperative controls are arranged 3 and 12 months after operation in a blinded manner by a physician not given the treatment.

Intervention Type
Procedure/Surgery

Primary outcome measure
Measured at baseline, 3 months and 1 year:
1. Valsalva maneuver based on physicians descriptive findings
2. Otomicroscopy based on physicians descriptive findings
3. Tympanometry results classified as A, B and C type outcomes
4. Tubomanometry results based on the Eustachian tube opening and opening latency index
5. Need for grommets

Secondary outcome measures
Quality of life measured with disease specific questionnaire ETDQ7 at baseline, 3 months and 1 year

Overall study start date
26/01/2017

Overall study end date
31/05/2022

Eligibility

Participant inclusion criteria
All patients in this study suffer from dilatory Eustachian tube dysfunction and are deemed suitable for BET. Possible indications are:
1. Persistent secretory otitis media
2. Severe symptoms of ETD
3. Baro-challenged ETD

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
165 (55 patients in each indication group)

Participant exclusion criteria
1. The occurrence of cleft palate in any form
2. Current ventilating grommet
3. Tympanic membrane perforation
4. Adhesive otitis
5. Cholesteatoma
6. Cystic fibrosis
7. Immotile cilia syndrome
8. Untreated nasal polyposis
9. Samter's triade
10. Untreated gastroesophageal reflux disease
11. Other mechanical obstruction in nasopharynx

Recruitment start date
27/11/2017

Recruitment end date
31/12/2020

Locations

Countries of recruitment
Finland

Study participating centre
Helsinki University Hospital
Surgical Hospital, Kasarmikatu 11-13

Helsinki
Finland
00029

Study participating centre
Turku University Central Hospital
Kiinamyllynkatu 4–8
Turku
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20521

Study participating centre
Tampere University Hospital
Teiskontie 35
Tampere
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33521

Sponsor information

Organisation
Helsinki University Hospital

Sponsor details
Kasarmikatu 11-13
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00029

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Government

Funder Name
State funding for University level health research

Funder Name
Research Foundation for ENT Disorders

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. Study protocol, statistical analysis plan, informed consent form, clinical study report and analytic code will be available immediately following publication.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other