ISRCTN02147658 https://doi.org/10.1186/ISRCTN02147658

Balloon Eustachian Tuboplast (BET)

Submission date 02/12/2011	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol
Registration date 28/12/2011	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 09/09/2013	**Condition category** Ear, Nose and Throat	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims?
The Eustachian tube is a narrow tube that connects the middle ear with the back of the nose. If it is blocked, it can cause muffled hearing or hearing loss, pain, a feeling of fullness in the ear. At the moment, persistent Eustachian tube dysfunction is commonly treated by inserting a tympanostomy tube (also known as a ventilation tube or grommet) through a small incision on the ear drum. Associated risks includes crusting, infection, obstruction and permanent tympanic membrane perforation. Repeated tube insertions may also be required. Special long-acting tubes are sometimes used but these are subject to increased risks. Patients with hearing loss may decide to use hearing aids. Balloon dilatation of the Eustachian tube is used in adults with the aim of
widening the Eustachian tube and improving its function.

Who can participate?
To take part the doctor needs to confirm that your Eustachian tube is blocked on one or both sides. Both male and female can participate, but you need to be 18 years or older.

What does the study involve?
Balloon dilatation of the Eustachian tube is usually performed with the patient under general anaesthesia. A balloon catheter is introduced into the Eustachian tube via the nose. Once the balloon is correctly positioned in the cartilaginous portion of the Eustachian tube, it is filled with saline up to a pressure of about 10 bars. Pressure is maintained for approximately 2 minutes. The balloon is then emptied and removed. Patients who have problems with both Eustachian tubes will be randomly allocated to one of two groups (either the right or the left side will be dilated). A tympanostomy tube (also known as a ventilation tube or grommet) will be inserted in the other ear.

What are the possible benefits and risks of participating?
The absence of an indwelling grommet is a significant benefit of the new procedure. The minimally invasive nature of the procedure reduces the possibility of complications. Risks may include damage or narrowing of the Eustachian tube, scarring, ear infection, pain and permanent hearing loss. In theory, there is a risk of rupture of a major artery (the internal carotid artery).

Where is the study run from?
North Bristol NHS Trust Hospitals.

When is study starting and how long is it expected to run for?
The anticipated start date is January 2012 (or soon after) and the approximate duration of the trial is two years. Follow up will continue for two years after.

Who is funding the study?
North Bristol NHS Trust

Who is the main contact?
Mrs Adenike Oluwasanmi
Adenike.Oluwasanmi@nbt.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Adenike Oluwasanmi

Contact details
ENT Department
Southmead Hospital
Westbury on Trym
Bristol
United Kingdom
BS10 5NB
+44(0)7985 544 850
Adenike.Oluwasanmi@nbt.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of Balloon dilatation on Eustachian Tube dysfunction: a randomised controlled study

Acronym
BET

Study objectives

Long-term Eustachian tube dysfunction is associated with damage to the eardrum and middle-ear transformer mechanism. Symptoms of this are: muffled hearing, pain, a feeling of fullness in the ear. Tinnitus or dizziness may also occur.

Hypothesis:
Dilating the Eustachian tube should improve its function and improve middle ear function thus reducing the incidence of diseases like glue ear etc

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Long-term Eustachian tube dysfunction

Interventions
Patients who has problems with both Eustachian tubewill be randomized to decide which side (right or left) to dilate. A tympanostomy tube(also known as a ventilation tube or grommet) will be inserted in the other ear.

A balloon catheter is introduced into the Eustachian tube via the nose, under transnasal endoscopic vision. Once the balloon is correctly positioned in the cartilaginous and bony portion of the Eustachian tube, it is filled with saline up to a pressure of about 10 bars. Pressure is maintained for approximately 2 minutes. The balloon is then emptied and removed

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Eustachian tube score (ear popping during swallowing and blowing the ears) at 1 to 2 week before dilatation and at 1 week, 1 month, 3 months, 6 months 12 months and 24 months after dilatation

Secondary outcome measures
1. Pure tone audiometry
2. Tympanometry

Measured at 1 to 2 week before dilatation and at 1 week, 1 month, 3 months, 6 months, 12 months and 24 months after dilatation

Overall study start date
04/01/2012

Completion date
04/01/2015

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
Patients with Eustachian tube dysfunction identified in the clinic will be invited to participate

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Children
2. Active nasal disease e.g. polyps, deviated septum

Date of first enrolment
04/01/2012

Date of final enrolment
04/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
ENT Department
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust (UK)

Sponsor details
ENT Department
Southmead Hospital
Westbury on Trym
Bristol
England
United Kingdom
BS10 5NB
+44 (0)117 950 5050
Adenike.Oluwasanmi@nbt.nhs.co.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

North Bristol NHS trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration