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

# Balloon Eustachian Tuboplast (BET)

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| **Submission date**<br>02/12/2011 | **Recruitment status**<br>Stopped | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>28/12/2011 | **Overall study status**<br>Stopped | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>09/09/2013 | **Condition category**<br>Ear, Nose and Throat | [_] Individual participant data<br>[_] 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
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# Contact information

### Type(s)
Scientific

### Contact name
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# Additional identifiers

### Protocol serial number
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

## Study type(s)
Treatment

## 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(s)
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

## Key secondary outcome(s))
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

**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

**Healthy volunteers allowed**
No

**Age group**
Adult

**Sex**
All

**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**
United Kingdom

England

**Study participating centre**
**ENT Department**
Bristol
United Kingdom
BS10 5NB

# Sponsor information

**Organisation**
North Bristol NHS Trust (UK)

**ROR**
https://ror.org/036x6gt55

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
North Bristol NHS trust (UK)

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |