# Role of Eustachian tube surgery in the treatment of chronic secretory otitis media

Submission date	Recruitment status	Prospectively registered
16/06/2021	Recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
08/07/2021	Ongoing	Results
Last Edited	Condition category	Individual participant data
09/05/2024	Ear, Nose and Throat	Record updated in last year

#### Plain English summary of protocol

Background and study aims

This study treats patients with chronic secretory otitis media (inner ear infection) by the techniques of balloon dilation of the eustachian tube (connect the middle ears to the back of the throat), tympanic (eardrum) tube placement, and a combination of both, and follows up their response and prognosis (eustachian tube function, hearing, and other indicators) to provide a data basis for optimal treatment plans for patients with chronic secretory otitis media in the future.

#### Who can participate?

Adults aged 18 to 70 years diagnosed with chronic secretory otitis media in China.

#### What does the study involve?

Patients diagnosed with chronic secretory otitis media were asked to participate in this study when they visit the hospital. Patients were randomly assigned to the balloon dilation of the eustachian tube (BDET), tympanic tube placement (Tube), and a combination of both (BDET+Tube) in a 1:1:1 ratio and received the corresponding surgical treatment. Clinical followup at 1 month, 3 months, 6 months, and 12 months after surgery. The study lasts three years in total.

### What are the possible benefits and risks of participating?

Patients may receive the same clinical benefit and potentially improved condition as with conventional eustachian balloon dilation or tympanic tube placement or a combination of the two. Potential complications associated with balloon dilation of the eustachian tube or tympanic tube placement may occur during or after the procedure.

#### Where is the study run from?

The study is being run by the Sixth Medical Center of PLA General Hospital and takes place in 21 hospitals across China.

When is the study starting and how long is it expected to run for? April 2021 to July 2027

Who is funding the study?
The Sixth Medical Center of PLA General Hospital (China)

Who is the main contact?
Dr. Zhaohui Hou, Houstone301@yahoo.com

# Contact information

#### Type(s)

Scientific

#### Contact name

Dr Zhaohui Hou

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# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

ChiCTR2100046672

# Study information

#### Scientific Title

Prospective, multicenter, randomized, controlled clinical study to evaluate the effectiveness of Eustachian tube surgical intervention in the treatment of chronic secretory otitis media

#### Acronym

**ETSICSOM** 

### Study objectives

Treatment with BDET has the opportunity to allow patients to avoid tympanic tube placement, or the possibility of enhanced outcomes with BDET in conjunction with tympanic tube placement.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved 07/05/2021, RB of Chinese PLA General Hospital (No.28, Fuxing Road, Haidian District, Beijing; +86(0)10-66957608; 301jgb@sina.com), ref: HZKY-PJ-2021-15

#### Study design

Multicenter interventional randomized parallel clinical study

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Surgical intervention of chronic secretory otitis media

#### **Interventions**

This study treats patients with chronic secretory otitis media by balloon dilation of the Eustachian tube (BDET), tympanic tube placement (Tube), and a combination of both (BDET+Tube). Block randomization method was adopted, and independent biostatisticians were responsible for generating random codes. According to the results of random grouping, researchers provided corresponding treatment for patients.

Subjects were randomly assigned to the BDET group, the BDET+TUBE group, or the TUBE group in a ratio of 1:1:1.

BDET group: The patients were treated with eustachian tube balloon dilatation surgery. Follow-up at 1 months, 6 months, and 1 year after surgery.

Tube group: The patients were treated with tympanic tube placement surgery. Follow-up at 1 month, 3 months, 6 months, and 1 year after surgery.

BDET+Tube group: The patients were treated with eustachian tube balloon dilatation surgery combined with tympanic tube placement surgery. Follow-up at 1 month, 3 months, 6 months, and 1 year after surgery.

#### **Intervention Type**

Procedure/Surgery

#### Primary outcome(s)

Eustachian tube dysfunction, measured using the eustachian tube score (ETS) at baseline and 12 months after the operation

#### Key secondary outcome(s))

- 1. Eustachian tube patency measured using recovery rate of Valsalva test at 3, 6 months
- 2. Hearing measured using pure tone audiometry at 6, 12 months
- 3. Morphology of tympanic membrane measured using otoendoscopy at 3, 6 months
- 4. Clearance of middle ear effusion measured using otoendoscopy at 1, 3 months
- 5. Eustachian tube dysfunction, measured using the ETS score 3, 6 months

#### Completion date

01/07/2027

# Eligibility

#### Key inclusion criteria

- 1. Age 18 to 70 years (including borderline values), with no restriction on gender
- 2. Patients diagnosed with chronic secretory otitis media, with no restriction on side, and those who meet the criteria in both ears can be included.
- 3. History of chronic secretory otitis media greater than 3 months.
- 4. Complete tympanic membrane with clear middle ear effusion on otoscopic examination.
- 5. Conductive deafness.
- 6. Acoustic conduction resistance with type B or C curve.
- 7. Negative for Valsalva.
- 8. History of previous tympanic membrane puncture or medication (nasal spray hormone and/or mucus promoter, etc.).
- 9. Patients who are to be treated with tympanic tube placement or eustachian tube balloon dilation for the first time and meet the indications for the surgery.

### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

### Upper age limit

70 years

#### Sex

All

#### Key exclusion criteria

- 1. Fluctuating sensorineural deafness.
- 2. Otoscopic examination of the tympanic membrane with adhesions to the tympanic capsule or the presence of otitis externa (oozing from the external ear canal, fungal infection, etc.)
- 3. Clear presence of abnormal opening of the eustachian tube or other eustachian tube diseases.
- 4. Eligible for surgical treatment due to other nasal, sinus or ear diseases.
- 5. History of surgery on the affected middle ear and nasal cavity or nasopharynx.

- 6. History of cleft palate or other deformities or related surgical repair.
- 7. History of head or neck surgery or radiation therapy
- 8. Patients with ciliary immobility syndrome.
- 9. Expected survival for malignancy <12 months.
- 10. Patients with other conditions that, in the opinion of the investigator, are not suitable for participation in this study.

#### Date of first enrolment

15/06/2021

#### Date of final enrolment

31/12/2026

# Locations

#### Countries of recruitment

China

# Study participating centre The Sixth Medical Center of PLA General Hospital

Beijing China 100037

# Study participating centre Eye&ENT Hospital of Fudan University

Shanghai China 200031

# Study participating centre Sun Yat-sen Memorial Hospital, Sun Yat-sen University

Guangzhou China 510120

#### Study participating centre Chengdu Second People's Hospital

Chengdu China 610031

# Study participating centre The First Affiliated Hospital of Zhengzhou University Zhengzhou China 450052

Study participating centre
Peking University, Shenzhen Hospital
Shenzhen
China
518036

Study participating centre Qilu Hospital of Shandong University Jinan China 250012

Study participating centre
The First Affiliated Hospital of Nanchang University
Nanchang
China
330006

Study participating centre
The First Affiliated Hospital of Chongqing Medical University
Chongqing
China
400016

Study participating centre
Xiangya Hospital Central South University
Changsha
China
410008

Study participating centre

#### Renmin Hospital of Wuhan University

Wuhan China 430060

# Study participating centre Tangdu Hospital

Xian China 710038

# Study participating centre The First Affiliated Hospital of Anhui Medical University

Hefei China 230022

# Study participating centre Peking University First Hospital

Beijing China 100034

### Study participating centre Foshan Second People's Hospital

Foshan China 528000

# Study participating centre Shengjing Hospital of China Medical University Shenyang

China 110004

#### Study participating centre

#### Yantai Yuhuangding Hospital

Yantai China 264001

#### Study participating centre Peking University Third Hospital

Beijing China 100191

# Study participating centre Peking Union Medical College Hospital

Beijing China 100730

# Study participating centre Shenzhen Longgang ENT Hospital

Shenzhen China 518172

## Study participating centre Foshan First People's Hospital

Foshan China 528300

# Study participating centre Third Affiliated Hospital, Sun Yat-Sen University

Guangzhou China 510000

# Study participating centre

#### Haikou People's Hospital

Haikou China 570100

Study participating centre Henan Provincial People's Hospital Zhengzhou China 450000

# Sponsor information

#### Organisation

The Sixth Medical Center of PLA General Hospital

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

The Sixth Medical Center of PLA General Hospital

# **Results and Publications**

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

All data generated or analysed during this study will be included in the subsequent results publication.

# IPD sharing plan summary

Other

#### **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information

Participant information sheet 11/11/2025 11/11/2025 No