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

**Submission date**
16/06/2021

**Recruitment status**
Recruiting

**Registration date**
08/07/2021

**Overall study status**
Ongoing

**Last Edited**
09/05/2024

**Condition category**
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 follow-up 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

### ORCID ID
https://orcid.org/0000-0003-1621-8242

### Contact details
The Sixth Medical Center of PLA General Hospital
No.6, Fucheng Road
Haidian District
Beijing
China
100037
+86 13810700293
houstone301@yahoo.com

# Additional identifiers

### 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

## Primary study design
Interventional

## Study design
Multicenter interventional randomized parallel clinical study

## 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 month, 3 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