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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
http://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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Secondary outcome measures
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

Overall study start date
01/04/2021

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex

Both

Target number of participants
480

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

Sponsor details
No. 6 Fucheng Road
Haidian District
Beijing
China
100037
+86 (0)1066957608
nghospital@sina.com

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/07/2027

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