

A randomised study to compare temporalis fascia and thin cartilage slices in eardrum repair

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/11/2013	Condition category Ear, Nose and Throat	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr MW Yung

Contact details
The Ear Nose and Throat Department
Ipswich Hospital
Heath Road
Ipswich, Suffolk
United Kingdom
IP4 5PD
+44 (0)1473 703 527
matthew.yung@ipswichhospital.nhs.uk

Additional identifiers

Protocol serial number
N0254119960

Study information

Scientific Title

Study objectives

Is there a difference in the efficacy and safety of the two most popular eardrum grafting materials, temporalis fascia and thin cartilage slices?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval was received from the local medical ethics committee in 2002 before trial recruitment began.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Ear, Nose and Throat: Eardrum repair

Interventions

Comparing temporalis fascia and thin cartilage slices.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Intact tympanic membrane

Key secondary outcome(s)

Hearing levels and air-bone gaps

Completion date

31/12/2008

Eligibility**Key inclusion criteria**

Patients with a larger eardrum perforation who require a surgical repair.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Perforations less than 75% size of the eardrum
2. Any patient who has a concomitant ossicular chain damage or fixation
3. Patients who do not have sufficient understanding of the information given to offer consent

Date of first enrolment

09/01/2003

Date of final enrolment

31/12/2008

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

The Ear Nose and Throat Department

Ipswich, Suffolk

United Kingdom

IP4 5PD

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

Ipswich Hospital NHS Trust (UK)

Funder Name

NHS R&D Support Funding

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?
Results article	results	01/08/2011		Yes	No