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

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

## 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.

## Study design

Randomised controlled trial

## Primary study design

Interventional

## 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

## 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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2	025 No	Yes