

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/11/2013	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> 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.

**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**

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?
<a href="#">Results article</a>	results	01/08/2011		Yes	No