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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 01/11/2013	**Condition category** 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

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 measure
Intact tympanic membrane

Secondary outcome measures
Hearing levels and air-bone gaps

Overall study start date
09/01/2003

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Patients with a larger eardrum perforation who require a surgical repair.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40 patients

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
England

United Kingdom

Study participating centre

The Ear Nose and Throat Department
Ipswich, Suffolk
United Kingdom
IP4 5PD

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Ipswich Hospital NHS Trust (UK)

Funder Name
NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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