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 12/09/2003	Overall study status Completed	Statistical analysis plan	
		[X] 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

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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 summaryNot 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