

A randomised study to compare hydroxyapatite and titanium prostheses in middle ear reconstruction

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/10/2010	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0254119959

Study information

Scientific Title

Study objectives

Is there a difference in the efficacy and safety of the two most popular ossicular prostheses hydroxyapatite and titanium?

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: Middle ear reconstruction

Interventions

Comparing hydroxyapatite and titanium.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Hearing levels and air-bone gaps

Secondary outcome measures

Extrusion of prosthesis

Overall study start date

10/01/2003

Completion date

31/12/2007

Eligibility

Key inclusion criteria

Any patient requiring an alloplastic ossicular prosthesis.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

100

Key exclusion criteria

Patients who do not have sufficient understanding of the information given to offer consent.

Date of first enrolment

10/01/2003

Date of final enrolment

31/12/2007

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)

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	01/07/2010		Yes	No