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

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/10/2010	Ear, Nose and Throat	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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