

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

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

Hearing levels and air-bone gaps

**Key secondary outcome(s)**

Extrusion of prosthesis

**Completion date**

31/12/2007

**Eligibility****Key inclusion criteria**

Any patient requiring an alloplastic ossicular prosthesis.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**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**

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)

# 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	01/07/2010		Yes	No