

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

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

### Contact name

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### Contact details

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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="#"><u>Results article</u></a>	results	01/07/2010		Yes	No
<a href="#"><u>Participant information sheet</u></a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes