

# Randomised pilot study of primary re-innervation of the larynx in patients undergoing vagal resection

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/08/2015	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**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**  
N0025157091

## Study information

**Scientific Title**

Randomised pilot study of primary re-innervation of the larynx in patients undergoing vagal resection

### **Study objectives**

To perform a pilot trial to assess whether dynamic methods of vagal nerve repair produce superior functional results to static repair techniques.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Randomised controlled pilot trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Surgery: Vagal resection

### **Interventions**

Pilot study

### **Intervention Type**

Procedure/Surgery

### **Phase**

Not Specified

### **Primary outcome(s)**

Not provided at time of registration

### **Key secondary outcome(s)**

Not provided at time of registration

### **Completion date**

01/12/2008

## **Eligibility**

### **Key inclusion criteria**

10 patients aged 16 and over undergoing resection of tumors related to the skull base where interruption of the vagus nerve is necessary to achieve tumour clearance.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

16 years

**Sex**

All

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/12/2004

**Date of final enrolment**

01/12/2008

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

AintreeTrust

Liverpool

United Kingdom

L9 7AL

**Sponsor information****Organisation**

Department of Health

**Funder(s)**

**Funder type**

Government

**Funder Name**

Aintree Hospitals NHS Trust (UK)

**Funder Name**

NHS R&D Support Funding

## **Results and Publications**

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration