

# 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

### Contact name

Mr Tristram Hugh John Lesser

### Contact details

AintreeTrust  
University Hospital Aintree  
Lower Lane  
L9 7AL  
Liverpool  
United Kingdom  
L9 7AL

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

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

## 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

Surgery: Vagal resection

## Interventions

Pilot study

## Intervention Type

Procedure/Surgery

## Phase

Not Specified

## Primary outcome measure

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/12/2004

**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

**Age group**

Adult

**Lower age limit**

16 Years

**Sex**

Both

**Target number of participants**

10 patients

**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**

England

United Kingdom

**Study participating centre**

**AintreeTrust**  
Liverpool  
United Kingdom  
L9 7AL

## Sponsor information

**Organisation**  
Department of Health

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

**Sponsor type**  
Government

**Website**  
<http://www.dh.gov.uk/Home/fs/en>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Aintree Hospitals NHS Trust (UK)

**Funder Name**  
NHS R&D Support Funding

## 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