

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

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 13/08/2015	Condition category Surgery	☐ Individual participant data ☐ 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