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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 13/08/2015	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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