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A double blind RCT of selective supraomohyoid neck dissection with/without level 2b for node negative oral cancer and resulting shoulder function

Submission date 29/09/2006	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 29/09/2006	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 27/11/2015	Condition category Cancer	Individual participant data

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

N0025177121

Study information

Scientific Title

A double blind RCT of selective supraomohyoid neck dissection with/without level 2b for node negative oral cancer and resulting shoulder function

Study objectives

The aim of the project is to compare patient derived and clinician rated morbidity, in terms of shoulder function, following a selective 1-3 level neck dissection in two groups of patients randomised for inclusion of level 2b in the neck and shoulder.

Ethics approval required

Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s) Not Specified

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

Cancer: Head and neck

Interventions

This will be a pilot study for a double blind randomised controlled trial. 60 patients requiring selective 1-3 level neck dissection as part of their overall treatment plan would be randomised as to whether they have a level 2b or not.

Assessment will be at 3 points: baseline, six weeks post operatively and 6 months. There will be monitoring for 2 years using existing follow-up protocols for neck node recurrence. Assessment will include: neurophysiology examination, clinical examination, self-completed guestionnaires.

Intervention Type Other

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 01/01/2006

Completion date 01/01/2009

Eligibility

Key inclusion criteria

 Patients with previously untreated oral cancer arising from the floor of the mouth and anterior two thirds of tongue who are neck node negative both clinically and on MRI scan.
 Requiring selective 1-3 level neck dissection as part of their overall treatment plan.

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants 60

Key exclusion criteria Not provided at time of registration

Date of first enrolment 01/01/2006

Date of final enrolment 01/01/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre AintreeTrust Liverpool United Kingdom L9 7AL

Sponsor information

Organisation Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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

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

Funder(s)

Sponsor type

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

Study outputs

Output type	
Results article	

Details Date created results 01/07/2012 Date added Peer reviewed?

Yes

Patient-facing?

No