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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 27/11/2015	**Condition category** Cancer	

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 questionnaires.

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
1. 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.
2. 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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2012		Yes	No