

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 27/11/2015	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Stanley Parikh

Contact details

AintreeTrust
University Hospital Aintree
Lower Lane
Liverpool
United Kingdom
L9 7AL
+44 0151 529 5283
sparikh@nhs.net

Additional identifiers

Protocol serial number

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

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

AintreeTrust

Liverpool

United Kingdom

L9 7AL

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - 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

Study outputs

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