

A randomised controlled trial of radical radiotherapy alone versus radical surgery plus radical radiotherapy for patients with cancer of the oral cavity

Submission date 01/07/2001	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 01/07/2001	Overall study status Completed	☐ Protocol
Last Edited 27/02/2015	Condition category Cancer	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

HN10

Study information

Scientific Title

A randomised controlled trial of radical radiotherapy alone versus radical surgery plus radical radiotherapy for patients with cancer of the oral cavity

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Head and neck cancer

Interventions

1. Arm A: Radical radiotherapy to the primary tumour and to the anterior triangles of the neck.
2. Arm B: Radical surgery involving wide local excision of the intra oral tumour with approximately a 1 cm margin and immediate reconstruction of the oral cavity. Neck dissection should be performed either for access to the oral cavity or for clearance of suspected clinically positive nodes. Following surgery patients receive radical radiotherapy to the primary tumour and to the anterior triangles of the neck.

Intervention Type

Mixed

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2005

Eligibility

Key inclusion criteria

1. Histologically proven squamous cell carcinoma of all grades at one of the following sites (except any patient with disease stage T1 N0): Tongue; Floor of mouth/alveolus; Retromolar trigone; Tonsil/lateral pharyngeal wall

2. Aged >18 years
3. No evidence of distant metastases beyond the regional neck nodes in the neck
4. No other malignancy, except basal cell carcinomas of the skin or intraepithelial carcinoma of the cervix
5. WHO performance status 0-2
6. Fit for radical surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1995

Date of final enrolment

31/12/2005

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

UK Co-ordinating Committee for Cancer Research (UKCCCR)

ROR

<https://ror.org/054225q67>

Funder(s)**Funder type**

Research organisation

Funder Name

Cancer organisations

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration