ISRCTN89427989 https://doi.org/10.1186/ISRCTN89427989

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 [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 27/02/2015	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
- - -

Contact details
UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Randomised controlled 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
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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1995

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
UK Co-ordinating Committee for Cancer Research (UKCCCR)

Sponsor details
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Sponsor type
Government

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Research organisation

Funder Name
Cancer organisations

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