The role of selective neck dissection in patients with early oral squamous cell carcinoma (1-3cm primary size) and no clinical evidence of lymph node metastases in the neck (N0)

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/04/2010		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/04/2010	Ongoing	[X] Results		
Last Edited	Condition category	[] Individual participant data		
17/07/2025	Cancer			

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-two-surgical-treatments-for-early-mouth-cancer

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00571883

Study information

Scientific Title

The role of selective neck dissection in patients with early oral squamous cell carcinoma (1-3cm primary size) and no clinical evidence of lymph node metastases in the neck (N0)

Acronym

SEND

Study objectives

- 1. To determine whether the use of a selective neck dissection used electively (hereafter referred to as SEND) on all patients presenting with T1 and T2 tumours and no clinical evidence of neck metastasis (N0) improves survival, disease-free survival and loco-regional disease control rates
- 2. To determine how SEND and complex reconstruction affect quality of life (QoL) and mental health
- 3. To determine whether the use of SEND on all patients presenting with T1 and T2 tumours and clinically N0 necks represents a cost-effective use of resources

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee North East – Northern & Yorkshire, 11/11/2006, ref: 06/MRE03/69

Study design

Randomised interventional treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Head and Neck Cancer; Disease: Head and Neck

Interventions

The trial will be a two-arm randomized trial:

Arm A: Patients will be allocated to have resection of the primary tumour with neck dissection

Arm B: Patients will be allocated to have resection of the primary tumour only

Follow up length: 96 months

Study entry: single randomisation only

Intervention Type

Other

Phase

Phase IV

Primary outcome(s)

Overall survival

Key secondary outcome(s))

- 1. Disease-free survival
- 2. Local and regional recurrence
- 3. Completeness of resection

Completion date

20/06/2026

Eligibility

Key inclusion criteria

- 1. Patients with oral squamous cell carcinoma (OSCC) measuring 1 to 3 cm at the primary site (ICD9 codes: 141, 143, 144, 145, 146, 149)
- 2. No clinical or preoperative imaging evidence of nodal involvement in the neck (N0 neck)
- 3. Surgery is the primary mode of treatment
- 4. Age 16 years and over, either sex
- 5. Capable of giving written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

All

Total final enrolment

596

Key exclusion criteria

- 1. Cancer of the lip (ICD9 code 140)
- 2. Previous head and neck tumour
- 3. Other synchronous tumour
- 4. Technical, medical or anaesthetic difficulties which preclude patients being entered into one of the trial arms

- 5. Where the surgeon assesses that the patient needs reconstruction that necessitates opening the neck
- 6. Those patients whom the multi-disciplinary team meeting considered to be medically, socially or psychiatrically unfit for surgery as first line treatment
- 7. Those patients where the patient expresses a preference for non-surgical treatment

Date of first enrolment 03/01/2007

Date of final enrolment 27/07/2015

Locations

Countries of recruitmentUnited Kingdom

England

Study participating centre St. Bartholomews Hospital W Smithfield London United Kingdom EC1A 7BE

Sponsor information

Organisation

Queen Mary University of London

ROR

https://ror.org/026zzn846

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2019	12/06/2020	Yes	No
Plain English results			25/10/2022	No	Yes