

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 23/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/04/2010	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English Summary

<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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00571883

Secondary identifying numbers

2069

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 hypothesis

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet**Condition**

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 measure

Overall survival

Secondary outcome measures

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

Overall study start date

03/01/2007

Overall study end date

31/07/2025

Eligibility

Participant 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

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

Planned Sample Size: 652; UK Sample Size: 652

Total final enrolment

596

Participant 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

Recruitment start date

03/01/2007

Recruitment end date

27/07/2015

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

St. Bartholomews Hospital

W Smithfield

London

United Kingdom

EC1A 7BE

Sponsor information**Organisation**

Queen Mary University of London

Sponsor details

Mile End Road
London
England
United Kingdom
E1 4NS

Sponsor type

University/education

Website

<http://www.qmul.ac.uk/>

ROR

<https://ror.org/026zzn846>

Funder(s)**Funder type**

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications**Publication and dissemination plan**

An initial paper was published in the British Journal of Cancer on the 15/10/2019 (the article is online with open-access and can be found at <https://rdcu.be/bVfLH>). Planned publication in a high-impact peer-reviewed journal with the results of the final analysis will be published around July 2026.

Intention to publish date

01/07/2026

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