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# 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

**Registration date**
23/04/2010

**Last Edited**
25/10/2022

**Recruitment status**
No longer recruiting

**Overall study status**
Ongoing

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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**
Ms Fran Ridout

**Contact details**
Saving Faces
1st Floor Grove Building
Mile End Hospital
275 Bancroft Road
London
United Kingdom
E1 4DG
+44 20 8223 8049
send@savingfaces.co.uk

## 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 |