

# 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)

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

## 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

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](mailto: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 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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet****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 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

## **Completion date**

31/07/2025

# **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

## **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

**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 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?
<a href="#">Results article</a>	results	01/11/2019	12/06/2020	Yes	No
<a href="#">Plain English results</a>			25/10/2022	No	Yes