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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