



SYNOPSIS

DAHANCA 22 SENTINEL EUROPEAN NODE TRIAL

*Sentinel Node Biopsy in the Management of
Oral Squamous Cell Carcinoma*

Primary objective: To establish that sentinel node biopsy (SNB) markedly reduces the incidence of elective neck dissection required in the management of the N0 neck.

Secondary objective: To describe the survival of SNB+ patients treated by neck dissection and relate it to that of SNB- cases with subsequent treatment for recurrent cervical disease. [descriptive only]

Tertiary objective: To establish if histological evaluation of the sentinel node by immunochemical and H&E section taken at 2.5mm intervals is adequate to detect tumour, or a more detailed evaluation by serial section is more appropriate

Primary end-points: Cervical recurrence-free rate 3 years after registration in the cohort of patients who are SNB- at registration. Secondary end-point: 1. Overall survival collectively, and by SNB status (SNB- or SNB+) but only descriptive. 2. PFS (progression-free survival) in the SNB- cohort. 3. Salvage rate of the SNB- patients who had a cervical recurrence during the first 3 years after registration. Patients should be followed up for five years or to death in order to establish survival. 4. QA (quality assessment) endpoint: false negative rate for part I and II of the pathology assessment.

Method and patients:

Design: Observational non randomised trial

Patient selection criteria:

- Primary biopsy proven oral squamous cell carcinoma.
- T1 and T2 tumours that can be locally resected*.
- Negative neck nodes (N0) based on imaging by either CT or MRI scans (ultrasound evaluation of the neck is operator dependent and not universally available). The standard of assessment for entry to the study is a N0 neck based on CT/MRI imaging.
- Patients must be preoperatively fit enough to withstand a neck dissection prior to inclusion into this trial.
- No previous neck pathology or treatment to the primary tumour or neck (surgery, radiotherapy or chemotherapy) that may alter lymphatic drainage channels.
- Age limit 18 – 75.

* This differs from the European protocol as only T1>1 cm and T2 are included.

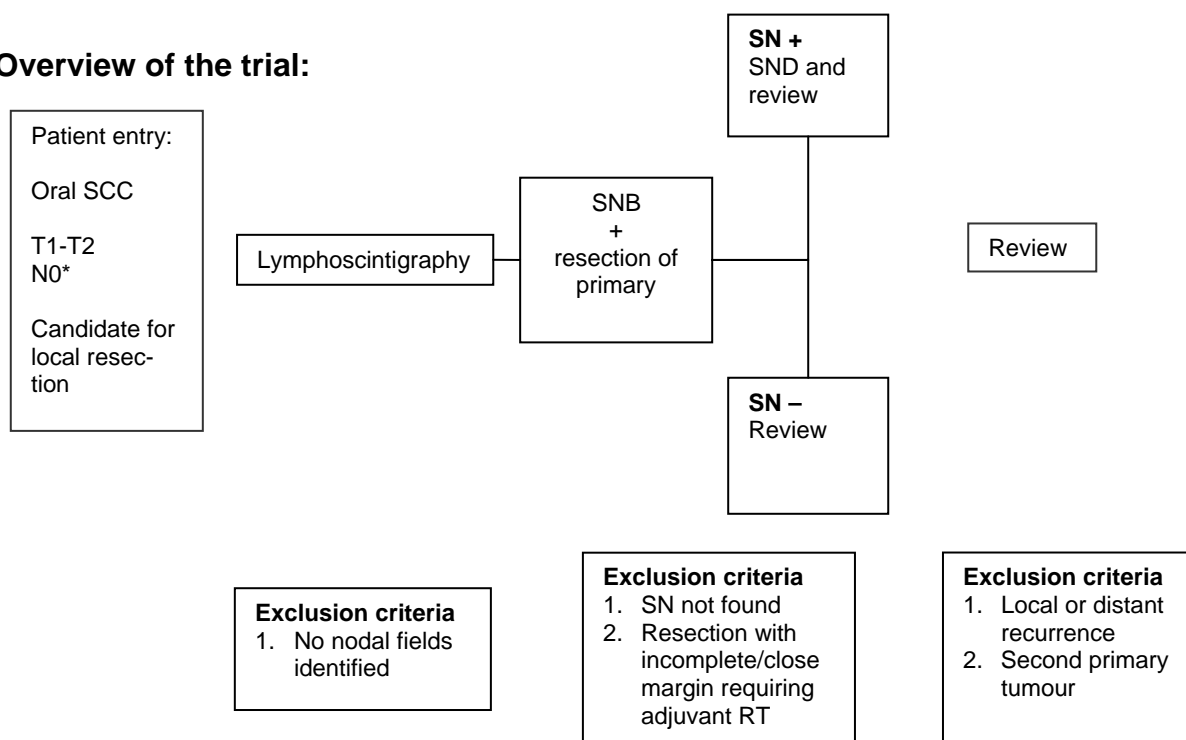


- WHO PS 0-2.
- Written informed consent.

Sample size:

- 430 patients need to be enrolled in this study. It is estimated that this patient number can be recruited over a period of 3 years.

Overview of the trial:



- Lymphoscintigraphy: 24-hr period prior to surgery the patients will be injected with 10-40 MBq of 99mTc labelled nanocolloid. Static or dynamic lymphoscintigraphy may be used depending on each centre's regulations.
- Histological examination of the SN. Part I (conventional histopathology) and part II (step serial sectioning) determines the status of the SN. The antibody used is cytokeratin antibody (AE 1/3).
- Review: All patients are followed for at least 5 years. The patients will be evaluated in the first year 5, 8 and 12 month after end of treatment. The second year at least every 4 months. The third to fifth year at least every 6 months.

DAHANCA Study group

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