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Accelerated RadioTherapy of Squamous Cell carcinoma of the head And Neck - study II: preoperative accelerated versus postoperative conventional radiotherapy in patients with resectable cancer of the oral cavity

Submission date 03/03/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/03/2008	**Overall study status** Completed	
Last Edited 16/06/2025	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Ver 1.1

Study information

Scientific Title
Accelerated RadioTherapy of Squamous Cell carcinoma of the head And Neck - study II: preoperative accelerated versus postoperative conventional radiotherapy in patients with resectable cancer of the oral cavity

Acronym
ARTSCAN II

Study objectives
To compare the efficiency of preoperative accelerated radiotherapy with postoperative radiotherapy, including chemotherapy for high-risk tumours, with respect to local control, disease free survival, overall survival and morbidity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Regional Ethical Review Board in Umea, Sweden on the 8th January 2008 (ref: 07-178M).

Study design
Open label randomised controlled multicentre study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Resectable squamous cell carcinoma of the oral cavity

Interventions
Patients will be randomised to:
1. Accelerated pre-operative radiotherapy with a concomitant boost technique. The treatment is given in two daily fractions (interval greater than seven hours), five days/week during four and a half weeks. The total dose is 68 Gy given in 34 fractions. Radical surgery should be performed in four to six weeks after completion of radiotherapy.
2. Radical surgery is performed up-front. Radiotherapy is started four to six weeks later with conventional fractionation, 2 Gy/fraction, five fractions/week for six weeks to a total dose of 60 Gy. High-risk patients (R1, R2 and/or lymph node metastasis with extracapsular extension) receive three additional fractions to a total dose of 66 Gy and concomitant chemotherapy with cis-platinum 50 mg/week, if there are no contra-indications.

The total duration of follow-up for all treatment arms is five years from start of treatment for each patient in both arms. Twelve months after inclusion of the last patient in the study main analysis will be done.

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Intervention Type
Mixed

Primary outcome(s)
Local and regional tumour control. Measurements will be done every three to four months during the first two years and every six months thereafter until five years have passed.

Key secondary outcome(s))
1. Survival:
1.1. Overall, measured with continuous monitoring
1.2. Cause specific, measured every three-four months during the first two years and every six months thereafter until five years have passed
2. Quality of life, measured before treatment start, after six months, one, two and five years
3. Morbidity related to tumour/treatment, measured every three-four months during the first two years and every six months thereafter until five years have passed

Completion date
28/02/2016

Eligibility

Key inclusion criteria
1. Over the age of 18 years, either sex
2. Resectable (as classified before surgery with radical intent), histological proven, previously untreated, squamous cell carcinoma of all grades and stages in the oral cavity without distant metastases. All T3-T4 and/or N2-3 tumours of the oral cavity can be included. Additionally T1-T2 and any N tumours of the oral cavity can be included provided the tumour is invading at clinical /radiological examination.
3. The tumour has to be judged as accessible for primary radical surgery and the patient must be expected to withstand combined surgery and radiotherapy
4. The patient must be able to understand the information about the treatment and give a written informed consent to participate in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
250

Key exclusion criteria
1. Previous anti-tumour treatment within three months before treatment
2. Evidence of distant metastases beyond the regional nodes in the neck
3. Co-existing disease prejudicing survival will exclude the patient (expected survival greater that six months)
4. Previous malignant disease in the head and neck region will exclude the patient with exception for basal cell carcinoma or curatively treated squamous cell carcinoma of the skin with follow-up time of at least three years
5. Adequate follow-up study must be possible; this will exclude a patient who is uncooperative

Date of first enrolment
18/02/2008

Date of final enrolment
01/02/2012

Locations

Countries of recruitment
Sweden

Study participating centre
Dept of ORL/Head & Neck Surgery
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Sponsor information

Organisation
Umea University Hospital (Sweden)

ROR
https://ror.org/012k96e85

Funder(s)

Funder type
Research organisation

Funder Name
The Swedish Cancer Society (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration.

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2022	13/04/2022	Yes	No
Results article	Perioperative complications in recently irradiated patients versus unirradiated patients	14/06/2025	16/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes