

# 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

<b>Submission date</b> 03/03/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/03/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/06/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

ClinicalTrials.gov number

Secondary identifying numbers

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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet (Swedish only)

### 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.

Joint contact details:

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## **Intervention Type**

Mixed

## **Primary outcome measure**

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.

## **Secondary outcome measures**

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

## **Overall study start date**

18/02/2008

## **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

260

**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 than 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**  
Lund  
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SE-22185

## **Sponsor information**

### **Organisation**

Umea University Hospital (Sweden)

### **Sponsor details**

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### **Sponsor type**

Hospital/treatment centre

### **Website**

[http://www.umu.se/umu/index\\_eng.html](http://www.umu.se/umu/index_eng.html)

### **ROR**

<https://ror.org/012k96e85>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

The Swedish Cancer Society (Sweden)

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration.

2019 results were to be presented at the International Conference on Head and Neck Oncology (ICHNO) in <https://user-swndwmf.cld.bz/7th-ICHNO-Abstract-book> abstract OC-005

### Intention to publish date

31/12/2019

### 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?
<a href="#">Results article</a>		01/01/2022	13/04/2022	Yes	No
<a href="#">Results article</a>	Perioperative complications in recently irradiated patients versus unirradiated patients	14/06/2025	16/06/2025	Yes	No