

# Patterns of loco-regional recurrence after conformal and intensity-modulated radiotherapy for head and neck cancer

<b>Submission date</b> 27/02/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/03/2017	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Head and neck cancer is a relatively uncommon type of cancer. Postoperative radiotherapy involves using doses of radiation to kill any cancer cells remaining after surgery to prevent the cancer from returning. If the radiation dose is inadequate or delivered to an inadequate area, this can lead to the tumour coming back (recurrence or relapse). The aim of this study is to look at the patterns of recurrence in head and neck cancer patients.

### Who can participate?

Head and neck cancer patients with relapse who have previously undergone radiotherapy

### What does the study involve?

Patient data is analysed to find out whether the relapse is related to the treatment they received. Radiotherapy data is analysed to look at the dose given in the primary tumour and relapse area in order to determine whether the relapse was the result of under-dosing of the primary tumour, and to find out whether treatment needs to be changed in order to avoid relapse in the future. There is no further treatment or follow up of the patients.

### What are the possible benefits and risks of participating?

Future head and neck patients may benefit if the reason for relapse is found and treatment is changed in order to avoid it. No risks are involved.

### Where is the study run from?

Oslo University Hospital (Norway)

### When is the study starting and how long is it expected to run for?

January 2015 to October 2016

### Who is funding the study?

Oslo University Hospital (Norway)

Who is the main contact?

Dr Safora Johansen

## Contact information

### Type(s)

Scientific

### Contact name

Dr Safora Johansen

### Contact details

Montebello

Oslo

Norway

0310

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2014/890

## Study information

### Scientific Title

Patterns of loco-regional recurrence after conformal and intensity-modulated radiotherapy for head and neck cancer: an observational retrospective study

### Study objectives

The aim of this study is to evaluate the patterns of loco-regional recurrences in head and neck cancer patients.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Committee for medical and research ethics south and east health region, 24/06/2014, ref: 2014/890

### Study design

Observational retrospective study

### Primary study design

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Head and neck cancer

**Interventions**

Patient data is retrospectively and anonymously analysed 4-5 years after completing treatment to find out whether the relapse is related to the treatment they received. The existing radiation data is analysed to see the dose in the primary tumour and relapse area in order to determine whether the relapse was the result of under-dosing of the primary tumour or not, and to find out whether treatment needs to be changed in order to avoid relapse in the future. There is no intervention or follow up of these patients.

**Intervention Type**

Other

**Primary outcome measure**

The site of tumor recurrence in comparison to primary tumor site, taken from existing patient data at 4-5 years after completing treatment

**Secondary outcome measures**

Radiation dose in the primary tumour and relapse area, taken from existing patient data at 4-5 years after completing treatment

**Overall study start date**

01/01/2015

**Completion date**

01/10/2016

**Eligibility**

**Key inclusion criteria**

1. Re-irradiation for first relapse in the head and neck region
2. Radiotherapy for both primary and recurrent disease at Oslo University Hospital
3. Computed tomography (CT), and/or positron emission tomography (PET)/magnetic resonance images (MRI) taken prior to radiotherapy
4. Available radiotherapy dose plans for the primary and recurrent disease which were

technically possible to co-register

5. Completed their planned curative primary radiation treatment

6. Aged 18 or over

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

26

**Key exclusion criteria**

Does not meet the inclusion criteria

**Date of first enrolment**

01/01/2015

**Date of final enrolment**

01/10/2016

## **Locations**

**Countries of recruitment**

Norway

**Study participating centre**

Oslo University Hospital

Oslo

Norway

0310

## **Sponsor information**

**Organisation**

Oslo University Hospital

**Sponsor details**

Montebello

Oslo

Norway

0310

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post@oslo-universitetssykehus.no

**Sponsor type**

Hospital/treatment centre

**Website**

<https://oslo-universitetssykehus.no>

**ROR**

<https://ror.org/00j9c2840>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Oslo University Hospital

## **Results and Publications**

**Publication and dissemination plan**

The manuscript is ready to be sent for publication in a radiation therapy journal

**Intention to publish date**

01/03/2017

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Jan Evensen (JFE@ous-HF.no)

**IPD sharing plan summary**

Available on request