

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

Submission date 27/02/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/03/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/03/2017	Condition category 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

ROR

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

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Oslo University Hospital

Results and Publications

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