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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	[_] Prospectively registered [_] Protocol
Registration date 06/03/2017	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 06/03/2017	**Condition category** Cancer	[_] Individual participant data [_] 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
-
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