A prospective, explorative cohort study to assess the value of an ex vivo radiosensitivity assay as a BIOmarker of treatment Response in Oropharyngeal Cancer (BIO-ROC).

Published: 15-07-2020
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Primary objective: to assess the relation of an ex vivo functional assay for tumor radiosensitivity with clinical tumor response of OPC patients treated with (chemo/bio-)radiotherapy at 3 months after treatment.Secondary objectives: - to assess the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON52756

Source
ToetsingOnline

Brief title
The BIO-ROC study

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
oropharyngeal cancer, throat cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biomarkers, Oropharyngeal cancer, Radiosensitivity assay, Radiotherapy

Outcome measures

Primary outcome

Esablishing the relation and the manner of the relation between the ex vivo functional assay for tumor radiosensitivity with clinical tumor response of OPC patients treated with (chemo/bio-)radiotherapy at 3 months after treatment.

Secondary outcome

- establishing the above mentioned relation in various treatment groups (such as: radiation only, chemo-radiotherapy, bioradiation with cetuximab, radiotherapy with protons instead of fotons)
- describing the effect of known prognostic factors (smoking, HPV-status, age, comorbidities) on the above mentioned relation
- establishing the relation of the of ex vivo functional assay for tumor radiosensitivity with locoregional tumor control of OPC patients treated with (chemo/bio-)radiotherapy at 2 years after treatment
- establishing the prognostic value, specificity and sensitivity of ctDNA as biomarkers of treatment response
- including every study patient in a repository of tumor biopsies and blood samples for future testing and validation of new (combinations of) biomarkers to predict treatment outcomes

Study description

Background summary

Radiotherapy with or without addition of systemic agents is the primary treatment choice for oropharyngeal cancer (OPC). Despite large heterogeneity in treatment response within OPC tumors, currently all patients receive an identical treatment. Currently there is no clinicaly validated test of a biomarker predictive of the therapy response. Consequently, patient with a good response receive potentially too intensive treatment, resulting in unnecessary toxicity. On the other hand, patients with resistent tumors require intensified treatment for tumor control. Ability to predict tumor response early in the treatment would have a major impact on the treatment choices of patients with OPC.

Within Erasmus MC a novel experimental assay has recently been developed, in which biopsy tissue of head-and-neck cancer is irradiated ex vivo to predict radiosensitivity of an individual tumor. This assay revelaed large differences in treatment response between investigated tumors. Within this study we want to perform a prospective cohort study to investigate the relation between the ex vivo radiosensitivity and clinical treatment respons of OPC patients. Furthermore, we want to establisch a biobank of OPC patients for future research on new biomarkers of treatment respons, such as circulating tumor DNA (ctDNA).

Study objective

Primary objective: to assess the relation of an ex vivo functional assay for tumor radiosensitivity with clinical tumor response of OPC patients treated with (chemo/bio-)radiotherapy at 3 months after treatment.

Secondary objectives:
- to assess the above mentioned relation in various treatment groups (such as: radiation only, chemo-radiotherapy, bioradiation with cetuximab, radiotherapy with protons instead of photons)
- to investigate the effect of known prognostic factors (smoking, HPV-status, age, comorbidities) on the above mentioned relation
- to assess the relation of the of ex vivo functional assay for tumor radiosensitivity with locoregional tumor control of OPC patients treated with (chemo/bio-)radiotherapy at 2 years after treatment
- to assess the prognostic value, specificity and sensitivity of ctDNA as biomarkers of treatment response
- to build a repository of tumor biopsies and blood samples of OPC patients for future testing and validation of new (combinations of) biomarkers to predict

treatment outcomes

Study design

Prospective explorative cohort study

Study burden and risks

Burden of the study consist of an additional biopsy of the tumor and four additional blood samplings. Those procedures will be integrated within the diagnostic workflow of the head-and-neck cancer patients and will require no additional hospital and/or outpatient clinic visits. The risk and impact on the patient*s quality of life are minimal and include a temporary bruising in the arm and moderate pain and/or minimal bleeding at the site of biopsy for a very short time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Clinical diagnosis of squamous cell carcinoma of the oropharynx, with or without histological confirmation
- In case of already histology-confirmed oropharyngeal cancer - primary tumor accessible for re-sampling without general anaesthesia
- Eligible for curative treatment with radiotherapy with or without the addition of systemic agents
- Written informed consent obtained
- Age >= 18 years

Exclusion criteria

- Patients with histology-confirmed oropharyngeal cancer, only accessible for re-sampling only under general anaesthesia
- Patients currently under treatment for other malignant disease (unless basal cell carcinoma of the skin)
- Previous radiotherapy in the head and neck area (with overlapping RT area)
- Recurrent oropharyngeal cancer

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-08-2020
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	15-07-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-08-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-04-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27421
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL73248.078.20
OMON	NL-OMON27421