Prospective study evaluating ctDNA as a biomarker for treatment response in head and neck squamous cell carcinoma*

Published: 12-04-2018
Last updated: 10-04-2024

To assess the kinetics of ctDNA in blood and saliva before, during and after definitive radiotherapy for HNSCC and to determine the prognostic value of ctDNA as predictor for treatment response in respect to conventional imaging.

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

Summary

ID

NL-OMON46578

Source
ToetsingOnline

Brief title
PECAN

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Head and neck cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: KWF + RT research

Intervention

Keyword: Biomarker, ctDNA, Head and neck cancer, Radiotherapy

Outcome measures

Primary outcome

To validate ctDNA after treatment as a predictor for the presence of residual disease and for the early detection of tumour recurrence.

Secondary outcome

1. The prognostic value of ctDNA during treatment as a biomarker for treatment response.

2. Timing and accuracy of ctDNA as a predictor for recurrence in comparison to conventional imaging.

3. The correlation of traceable mutations found in blood / saliva in comparison to mutations found in tissue biopsies, as a parameter for tumor heterogeneity.

4. The tumours* genomic status and epigenetic evolution over time under pressure of radiotherapy.

5. Sensitivity and specificity of ctDNA in blood compared to saliva.

6. The correlation between ctDNA before treatment and other clinical/biological parameters in the prediction of disease recurrence.

Study description

Background summary

Tumours continually shed DNA into the circulation, where it can be accessed. This circulating tumour DNA (ctDNA) directly reflects tumour burden and has great potential to be a sensitive biomarker for treatment recurrence. These *liquid biopsies* could give a more real-time picture of the genomic status and

evolution of a tumor and can be easily assessed for measurement of different biomarkers. However, in head and neck squamous cell carcinoma (HNSCC) patients treated with definitive radiotherapy, data regarding ctDNA kinetics and its correlation with outcome are scarce. A new or additional tool for response evaluation next to or instead of conventional imaging after treatment would be beneficial to detect recurrences in an earlier stage, thereby increasing the chances of success of salvage therapy. More importantly, an early response parameter during treatment could help to identify patients that have a good treatment response and might benefit from treatment adaptation. With this study, we aim to reveal ctDNA as an effective tool for future dose (de)-escalation trials in HNSCC.

Study objective

To assess the kinetics of ctDNA in blood and saliva before, during and after definitive radiotherapy for HNSCC and to determine the prognostic value of ctDNA as predictor for treatment response in respect to conventional imaging.

Study design

Prospective non-randomized observational study.

Study burden and risks

Blood and saliva will be collected at regularly planned outpatient visits. This will be once before start of treatment, at 6-7 different moments during treatment and at five moments after end of treatment (38ml each). Tumor and germline DNA will be analyzed using sequencing techniques. Therefore, there is a small possibility of detection of unsolicited findings, i.e. germline DNA variants that confer an increased risk of developing malignancies or other diseases both for the patient and his/her family. In total, 3 extra conventional CT scans or MRI scans will be performed during follow up. These extra scans will be accompanied by (an acceptable amount of) radiation burden. The possible advantages of these extra scans will be very stringent follow up, with the possibility of more early and adequate therapeutic salvage treatment.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
AMSTERDAM 1066CX
NL

Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
AMSTERDAM 1066CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• >= 18 years of age
• Stage II-IV carcinoma of the larynx, hypopharynx, oral cavity or HPV negative oropharynx, or stage II-III HPV positive oropharyngeal carcinoma, according to the American Joint Committee on Cancer (AJCC) staging manual 8th edition
• Indication for curative radiotherapy with or without concurrent radiosensitizer
• WHO performance status 0-2
• signed written informed consent

Exclusion criteria

• Metastastic disease
• Radiotherapy with palliative intent
• Diagnosis of any other malignancy within 5 years prior to start of treatment except for adequately treated basal cell or squamous cell skin cancer, or carcinoma in situ of the breast or of the cervix, or low-grade (Gleason 6 or below) prostate cancer on surveillance with no plans for treatment intervention (e.g. surgery, radiation or castration).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-08-2018
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	12-04-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	28-06-2019
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL64571.031.18