Immune sparing Radiotherapy strategies In head and neck Squamous cell carcinoma (IRIS)

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To study the immune effects of novel radiotherapy schedules by longitudinal immune profiling. There will be a specific focus on actionable immune targets and their temporal patterns that can be tested in future immune-radiotherapy combination trials...

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

Summary

ID

NL-OMON56801

Source
ToetsingOnline

Brief title
IRIS study

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
head and neck cancer (HNC), head and neck squamous cell carcinoma (HNSCC)

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: Immune system, Immunosuppression, Lymphodepletion, Radiotherapy

Outcome measures

Primary outcome

* Numbers of immune cell populations and frequency of T cell subsets according to markers of maturation, activation, co-signaling and chemo-attractant receptors at baseline, related to patient- and tumor characteristics (tumor localization, TNM status, tumor subtype, comorbidities etc.).

* Temporal changes of immune markers obtained in blood during/after treatment at 6 timepoints (baseline, 2 weeks during RT, end of RT, 2 weeks after RT, 6 weeks after RT and 3 months after RT).

Secondary outcome

n.a.

Study description

Background summary

Radiotherapy (RT) for advanced-stage head and neck squamous cell carcinoma (HNSCC) results in an unfavorable 5-year overall survival of 40%, and there is a strong biological rationale for improving outcome by combinatorial treatment with immunotherapy. However, also immunosuppressive effects of radiotherapy have been reported and recently a randomized phase-III trial failed to show any survival benefit following the combination of a PD-L1 inhibitor with chemoradiotherapy. It is hypothesized that the combination of these individually effective treatments failed because of radiation-induced lymphodepletion and that the key therefore lies in reforming conventional radiotherapy, which typically consists of large lymphotoxic radiation fields of 35 fractions. With the current study, we build a biobank for future immunologic profiling to explore Immune sparing Radiotherapy strategies In head and neck Squamous cell carcinoma (IRIS). Based on the acquired knowledge we may be able to reshape conventional radiotherapy for future effective immune-radiotherapy

combinations.

Study objective

To study the immune effects of novel radiotherapy schedules by longitudinal immune profiling. There will be a specific focus on actionable immune targets and their temporal patterns that can be tested in future immune-radiotherapy combination trials.

Study design

Biobank study of peripheral blood samples obtained at baseline, 2 weeks during RT, end of RT, 2 weeks after RT, 6 weeks after RT and 3 months after RT.

Study burden and risks

To study the immune effects during and after treatment, patients will be asked for 6 blood draws in total (2x10mL EDTA each time) during regular visits to the outpatient clinic. Blood will be collected by vena punctures, which may cause only slight physical discomfort. There will be no extra study related physical examinations, tests or questionnaires.

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

Patients with mucosal squamous cell carcinoma of the head and neck amenable for radiotherapy

Exclusion criteria

• Previously treated by irradiation in the head and neck region
• Chronic inflammatory disease or immune disorders
• Other malignant disease (unless in situ carcinoma or BCC) within the last 2 years.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2024
Enrollment:	42

Type:	Anticipated

Ethics review

Approved WMO Date:	03-06-2024
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL85175.078.23