Immune profiling of tumor and blood of patients with nasopharyngeal cancer

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To determine local and systemic immune markers, with emphasis on T lymphocytes, in primary and recurrent NPC patients and investigate how these immune markers correlate to clinical response to CR in NPC. Primary Objective1:Profile whole blood and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON51134

Source
ToetsingOnline

Brief title
IM-NPC

Condition

- Other condition

Synonym
nasopharyngeal carcinoma

Health condition

Nasopharynx cancer

Research involving
Human

Sponsors and support

Primary sponsor: Select
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chemoradiotherapy, Immune profiling, nasopharyngeal carcinoma

Outcome measures

Primary outcome

• Systemic immune parameters and their correlation to recurrence free survival

and EBV titers

• Local immune parameters and their correlation to recurrence free survival

and EBV titers

Secondary outcome

• Differences in systemic and local immune markers between primary and

recurrent NPC

• Kinetic changes in systemic and local immune parameters upon treatment

• Correlation between systemic and local immune parameters

Study description

Background summary

Nasopharyngeal carcinoma (NPC) is highly prevalent in southeast Asia. Chemoradiation (CR) is currently the primary treatment modality for locally advanced disease. However, approximately 40% of the patients develop recurrent NPC.
Undifferentiated NPC is commonly associated with Epstein Barr virus which can cause dysregulation of the NF-Kb pathway leading to an inflammatory response in NPC . However recurrent NPC patients upregulate immunosuppressive mechanisms to downregulate the immune response to NPC. In order to develop better therapeutic strategies, it is a prerequisite to perform in-depth analysis of systemic

(i.e., blood) as well as local (i.e., tissue) immune markers of NPC patients treated with CR. These analyses could reveal immune-suppressive mechanisms employed by NPC that can provide potential targets for immunomodulatory drugs to be used in combination with CR to enhance its clinical efficacy.

Study objective

To determine local and systemic immune markers, with emphasis on T lymphocytes, in primary and recurrent NPC patients and investigate how these immune markers correlate to clinical response to CR in NPC.
Primary Objective1:
Profile whole blood and PBMCs of NPC patients who are undergoing CR treatment for immune cell numbers and phenotype (with emphasis on T cell subsets).
Second Objective(s):
Profile tumor tissue of NPC patients who are undergoing CR treatment for ICD, type I IFNs and T cell evasion.
Third Objective(s):
Correlate systemic as well as local immune markers to clinical outcomes like recurrence free survival.
Fourth Objective(s):
Profile plasma (immune mediators and EBV titers) and PBMCs (T cell functions and TCR repertoire) of NPC patients who undergo CR treatment, and correlate these markers to above-mentioned immune markers, clinical outcomes and EBV titers.

Study design

All patients with confirmed NPC diagnosis will be treated with 35 fractions of 2 Gy radiotherapy and 7 weekly cycles of 40 mg/m2 cisplatin. Patients will be followed for 2 years. Blood is collected at the time of diagnosis, and at different time points during treatment and follow up. Tissue is collected during confirmatory biopsy and during follow up in case of recurrence or residual disease. Whole blood and cryopreserved PBMCs are being used to perform multiplex flow cytometry analysis. Tumor tissues will be processed into FFPE samples for immunofluorescence. Plasma of NPC patients will be used to isolate EBV DNA and measure chemokine expression using ELISA.

Study burden and risks

The current study does not pose any risk to the patients, and the only burden is collection of additional blood during (already scheduled) blood collections and an additional biopsy during diagnostic biopsy. The study has no direct benefit for the included subjects. However, the results of this study are expected to lead to optimization of therapeutic strategies for NPC patients in the future.

Contacts

Public
Select

Dr Molewaterplein 40
rotterdam 3015 CE
NL
Scientific
Select

Dr Molewaterplein 40
rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Age >=18 years
• Able to understand the written information and able to give informed consent
• Should have histologically confirmed NPC
• Planned treatment with CR for locoregionally advanced NPC

Exclusion criteria

• Unable to draw blood for study purposes
• Any coexisting condition which needs immediate treatment and which might affect the results of the study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2021
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-06-2021
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	NL75598.078.20