Immunogenic Targets for Therapeutic Vaccination for Liver Cancer

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To compare numbers of circulating T cells responding to different tumour-associated and viral antigens, as well plasma concentrations of antibodies against these antigens, before and after therapeutic interventions that destruct or debulk tumour...

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON42346

Source
ToetsingOnline

Brief title
ITVALICA

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
liver cancer, primary liver cancer

Research involving
Human

Sponsors and support

Primary sponsor: Maag Darm Leverziekten, Clinical Research Bureau
Source(s) of monetary or material Support: Ministerie van OC&W,China Scholarship Council

Intervention

Keyword: antibody response, hepatocellular carcinoma, T-cell response, tumor antigen

Outcome measures

Primary outcome

Determination of tumour antigens and viral antigens that are target of

naturally occurring T cell and antibody responses upon tumour destruction or

debulking by currently applied therapeutic interventions.

Secondary outcome

None

Study description

Background summary

Hepatocellular carcinoma (HCC) is the most prevalent primary liver cancer. HCC develops most often in patients with liver cirrhosis, and can be caused by different aetiologies, among which chronic hepatitis B virus (HBV) or HCV-infection. In addition, HCC can develop in non-cirrhotic livers due to unknown etiology. For 80% of HCC-patients no curative therapy is currently available, and HCC is notoriously resistant to chemotherapy. Immunotherapy represents an attractive alternative treatment option, because it is highly specific and can induce long-lasting immunological memory that may permanently prevent tumor recurrence.

Our ultimate goal is to develop innovative therapeutic vaccination protocols for HCC. To identify immunogenic candidate antigens for inclusion in future vaccines, we aim in the present study to determine which tumour- and viral antigens induce spontaneous T-cell and antibody responses in HCC-patients after treatments that stimulate release of such antigens from tumour tissue or reduce the immunosuppressive tumour microenvironment. For this purpose, we will compare systemic T-cell and antibody responses against different tumour- and viral antigens before and after local tumour destruction by radio-frequency ablation (RFA), trans-arterial chemo-embolization (TACE), or debulking of tumour tissue by surgical resection.

Study objective

To compare numbers of circulating T cells responding to different tumour-associated and viral antigens, as well plasma concentrations of antibodies against these antigens, before and after therapeutic interventions that destruct or debulk tumour tissue.

Study design

Cohort study in HCC-patients which are treated by RFA, TACE, or surgical resection. Blood will be collected before intervention, at 3 and 6 weeks after intervention to determine primary T-cell and antibody responses, and at 3 months after intervention to determine memory T-cell and antibody responses. Numbers of CD4+ and CD8+ T cells that respond to different tumour- and viral antigens will be determined by state-of-the-art ex vivo techniques, and antigen-specific antibodies will be quantified by ELISA. In addition, leukocytes and plasma will be stored frozen in a biobank for future studies.

Study burden and risks

Collection of 80 ml blood at 4 time points. Two of these collections will be done during regular venous drawings for diagnostic purposes. No benefit or high risk for these patients. Hopefully the results of the study will benefit future HCC-patients.

Contacts

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Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult HCC-patients treated with RFA, TACE, or surgical resection in Erasmus MC, who are planned to be followed up in Erasmus MC for at least 3 months after the intervention.

Exclusion criteria

Patients who refuse to participate in the study (refusing blood/tissue donation).
Patients with a severe immunocompromised medical condition, or patients taking immunosuppressing medication.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	360
Type:	Anticipated

Ethics review

Approved WMO Date:	20-10-2015
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	NL54160.078.15