Charting Survivin specific T cells in cancer patients with Head and Neck Squamous Cell Carcinoma

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Primary objective; Ex vivo charting of T cell reactivity directed against the tumour antigen survivin in peripheral blood of HNSCC patients. Secondary objective; Ex vivo charting of T cell reactivity against tumour antigens other than survivin....

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

Summary

ID

NL-OMON33346

Source
ToetsingOnline

Brief title
Charting Survivin specific T cells in HNSCC patients

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Head and Neck cancer, HNSCC

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: KWF

Intervention

Keyword: HNSCC, Immunotherapy, Survivin, T-cells

Outcome measures

Primary outcome

Primary; Charting the presence of tumour specific T cells will be performed employing tetramer staining. In house made HLA-A1 and HLA-A2 tetramers will be used to detect T cells directed against known antigenic peptide sequences derived from the tumour antigen survivin. This will document the presence of T cells with such specificities as a percentage of total CD8 positive T cells. It is expected that in about half of the patients survivin specific T cells will be detectable.

Secondary outcome

Secondary; Since tetramers are available containing antigenic peptides derived from tumour antigens other than survivin, it is possible to chart the immune reactivity against these antigens simultaneously. We will do so employing tetramers with a fluorescent marker different form the one used for survivin.
Tertiary; Tetramer positive T cells will be isolated from these samples when possible.

Study description

Background summary

Cancer specific T cell reactivity can aid substantially in the destruction of growing tumours and distant metastasis. Potentiating the efficacy of such T cell reactivity can be achieved by vaccination of cancer patients with (autologous) dendritic cells loaded with immunogenic tumour antigens. Charting

naturally occurring T cell reactivity against predefined tumour antigen(s) in HNSCC patients will help in the design of a potent dendritic cell based vaccine. Peripheral blood can be used as a source of such T cells, this does not interfere with diagnosis or treatment outcome.

Study objective

Primary objective; Ex vivo charting of T cell reactivity directed against the tumour antigen survivin in peripheral blood of HNSCC patients. Secondary objective; Ex vivo charting of T cell reactivity against tumour antigens other than survivin. Tertiary objective; Isolation of tumour specific T cells from the same samples.

Study design

This is an observational study from which the participating patients will not benefit. Peripheral blood will be drawn just once and some time after the patients have received standard treatment. Prior treatment can consist of surgery, radiotherapy and/or chemotherapy. In order not to interfere with these treatments blood will not be drawn before treatment. In case the patient also received chemotherapy a period of rest will be observed for the immune system to recover.

Study burden and risks

Patients will be asked to donate a single blood sample of 120 ml. The blood sample will be collected using a butterfly needle in order to minimize the burden of changing heparin containing vacuum tubes.

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

The patients in this study must have a histological confirmation of Head and Neck carcinoma stage 3 or higher.
Patients must be over 18 years of age. There is no maximum age.
Patients must be capable of giving informed consent.
Patients must have a life expectancy of at least 3 months.
Patients must be HLA-A2 positive.

Exclusion criteria

Patients are excluded when pregnant.
Patients are excluded when anemic.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	22-10-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL28567.029.09