Identification of mutated and non-mutated tumor-associated antigens in glioblastoma

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Primary: The major aim is to identify peptides naturally presented on glioblastoma tumors but not on healthy tissue to set up a glioblastoma specific database for potential application for immunotherapeutic aproaches.secondary: a protocol for tumor...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON38803

Source
ToetsingOnline

Brief title
GAPVAC (Glioma actively personalized vaccine consortium) part 1

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
glioblastoma, glioblastoma multiforme

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: EU FP7 project

Intervention

Keyword: Glioblastoma, personilized vaccine, tumor associated peptide

Outcome measures

Primary outcome

Mutated and non-mutated tumor-associated antigens in glioblastoma

Secondary outcome

EU harmonized procedures for imuunmonitoring.

A glioblastoma specific sHLA:peptidome.

Study description

Background summary

Glioblastoma is a fatal disease with a median survival of less than 1.5 years. One novel promising approach in oncology is activation of the patient's own immune system against the cancer by vaccinations to evoke an immune response leading to elimination of the malignant cells.

Study objective

Primary: The major aim is to identify peptides naturally presented on glioblastoma tumors but not on healthy tissue to set up a glioblastoma specific database for potential application for immunotherapeutic aproaches.
secondary: a protocol for tumor infiltrating lymphocytes (TILs) extraction of tumor samples of glioblastoma patients will be set up for use in later clinical development. Moreover, the glioblastoma specific sHLA:peptidome will be identified from plasma samples of patients for use as surrogate biomarker in later clinical trials.

Study design

Patients will be informed both by personal communication about the study in conjunction with an ordinary visit prior to surgery and in a written form.
At the day of surgery blood (20 ml) will be drawn for plasma sample preparation, HLA typing and genomic analysis. Part of the tumor tissue that has been removed during standard surgery will, if possible, be colected for mutation, peptide presentation, proteomics analysis and TIL analysis.

2-12 weeks post surgery another blood sample (10 ml) will be drawn for plasma sample preparation at a regular visit.

Study burden and risks

All blood samples will be drawn during routine visits of the patient within standard therapy. venous bloodsampling may cause local pain or bruising. No additional study specific risk will occur from tumor sample analysis, sinc stumor analysis will be perfomed on tumor samples removed during routine surgery

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

Age: >= 18 years
• Unresected primary or recurrent brain tumor
• Haemoglobin >= 10 g/100 ml
• Able to understand the research and give written informed consent

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-04-2013
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO

Date:	24-04-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL43349.058.13