Development of Dendritic Cell vaccines as future treatment of patients with cancer

Published: 17-08-2017
Last updated: 15-04-2024

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

Summary

ID

NL-OMON55686

Source
ToetsingOnline

Brief title
Anti-cancer DC vaccine development

Condition

- Other condition

Synonym
NA

Health condition

het betreft enkel afname van bloedcellen via aferese bij gezonde vrijwilligers voor verbeteren en optimaliseren productie methode cellulaire immunotherapie

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Apheresis, cancer, Dendritic Cell vaccine, ex vivo generation

Outcome measures

Primary outcome

The primary outcome that is relevant:

1. a strong T cell response in vitro with a readout of Interferon gamma

production.

Secondary outcome

NA

Study description

Background summary

The dendritic cell is the master switch of the immune system and the key player in priming an immune response. In patients with established cancer, the dendritic cells have not been able to initiate a potent enough immune response or the tumor suppresses or deceives and escapes from the immune response. Dendritic cell vaccines are developed to (re-)generate or initiate a strong anti- tumor immune response.

Study objective

The proposed research is part of our ongoing research of the last 17 years. Development of immunotherapy for cancer is our main theme and DC vaccines is our oldest program and play a crucial role.
At this moment still 40% of cancer patients die of their disease. Het remains therefore extremely urgent and relevant to acquire knowledge in this field that can be used to ultimately be able to give new therapies to patients.
The current application proposed to the MECT has at the central aim to acquire knowledge in the field that will allow us to further develop and improve our DC

vaccine in the laboratory. As it will later be applied in patients, the material has to be of human origin.

The objective of the current study is to:
1. investigate the conditions to obtain the most optimal T cell stimulation in vitro by the DC vaccine.

Study design

1. The study is an in vitro study. The apheresis product will be transfered to the laboratory and white blood cells will be cultured in vitro. Monocytes will be differentiated to dendritic cells that in turn will be used in T cell stimulation assays.

Study burden and risks

The volunteers will receive a physical examination to determine their health status and fitness for the apheresis process. At the same time one tube of blood will be drawn and used to determine blood values. When donors are fit, they will be subjected on a different day to the apheresis that will last for 4 hours. Before the start, one tube of heparinised blood will be drawn to determine base values.
The risks for complications and side affects are very low, therefore the study is justified.

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

Healthy volunteers, no underlying disease
Age 18 or older
Male or Female

Exclusion criteria

no venous access

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2018
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	17-08-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-01-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL60859.068.17