Generation of Dendritic cells from patients with breast cancer, multiple myeloma or ovarian cancer

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To study (in vitro) if dendritic cells can be cultured with cells obtained from peripheral blood of patients with either m. myeloma, ovarian cancer or breast cancer. Thusfar we worked with cells from healthy volunteers. Before performing clinical...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Haematopoietic neoplasms (excl leukaemias and lymphomas)
Study type	Observational non invasive

Summary

ID

NL-OMON33883

Source
ToetsingOnline

Brief title
Production of Dendritic cells from patients

Condition

- Haematopoietic neoplasms (excl leukaemias and lymphomas)
- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Breast Cancer, Multiple Myeloma, Ovarian Cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: breast cancer, cancer vaccin, Dendritic cells, multiple myeloma, ovarian cancer

Outcome measures

Primary outcome

Can we collect enough and adequate dendritic cells from the group of patients

defined above, in our facility and using our culture system.

For clarity: there will be no add back of the cells to patients in this study

Secondary outcome

not relevant.

Study description

Background summary

Since this is a local study the description in English is more limited than the Dutch description. If a more extensive description (translation from dutch) is necessary please let me know.

In our clinical research group the focus is on immunotherapy for blood cancers and solid tumours, mainly breast cancer.
Development of a vaccin, using Dendritic cells, is one of the goals. We have optimised the culture of dendritic cells in vitro and selected the system that we want to use in vivo (Manuscript in preparation). Before performing clinical studies using dendritic cells we have to analyse if dendritic cells obtained from patients are equally good than the ones used from healthy volunteers thus far (see objective of the study).

Study objective

To study (in vitro) if dendritic cells can be cultured with cells obtained from peripheral blood of patients with either m. myeloma, ovarian cancer or breast cancer. Thusfar we worked with cells from healthy volunteers. Before performing clinical studies (i.e. adding back the dendritic cells to the patient as a vaccin) we intend to study the quality of the DC obtained from patients. Study questions are: adequate number of cells, adequate phenotype of

the DC and adequate cytokine profile of the DC.

Study design

Patients will donate blood via a leucapheresis procedure. They will have an infusion system in both arms, one for collecting the cells and one for add back of the blood without the leucocytes. (This leukapheresis procedure is comparable to dialysis in kidney patients).
The procedure will take about 2 to 3 hours to collect enough cells.
The procedure is a routine procedure in the hospital for bone marrow stem cell donors (about 80 procedures per year).

Study burden and risks

Patients will undergo a leukapheresis procedure as described above. A standard operating procedure will be followed (protocol number AZM 15192). In case of clinical problems (not to be expected) the procedure will be stopped. It might be that patients with m. myeloma have had this procedure before, since it is part of the standard treatment protocol untill a certain age to give high dose chemotherapy and add back of stem cells. They can argue very well if they want to perform the procedure a second time for the purpose of research only.

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

patients with either breast cancer, ovarian cancer or Multiple Myeloma, that did not receive any systemic therapy during the previous three months. (Hormonal therapy is accepted in case of breast cancer). For details of inclusion: see paragraph D4b.

Exclusion criteria

Recent (3 months) systemic therapy. In more detail: see D5b.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-06-2010
Enrollment:	9
Type:	Actual

Ethics review

Approved WMO

Date:	15-07-2009
Application type:	First submission
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	NL22622.068.08