Protocol NKI-AVL: blood sampling of healthy volunteers for immunological research

Published: 24-01-2019
Last updated: 11-04-2024

To compare the immunobiology of healthy volunteers to (advanced) cancer patients to age-matched controls with no history of cancer and no potentially interfering medication.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Immune disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON45890

Source
ToetsingOnline

Brief title
Blood sampling of healthy volunteers

Condition

- Immune disorders NEC

Synonym
Immunobiology

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: healthy volunteers

Outcome measures

Primary outcome

Primary objective: mapping immune effector and suppressor functions in healthy individuals, to be used as a tool in immuno-oncology research

Secondary outcome

Secondary objectives:

- Assessing and comparing the functionality of viral-epitope specific CD8+ T cells in healthy volunteers with the functionality of viral-epitope specific CD8+ T cells in cancer patients to gain insights into the possibility of a systemically *exhausted* CD8+ T cell state in these patients

- Immunophenotyping of both myeloid and lymphoid cells in healthy controls to gain insights in immunological defects and immune evasion in cancer patients

Study description

Background summary

We hypothesize that the immune system of cancer patients becomes more dysfunctional as the disease progresses and that there is less immunosuppression and/or immune evasion in healthy volunteers and early stage cancer patients, as compared to patients with advanced disease.

Study objective

To compare the immunobiology of healthy volunteers to (advanced) cancer patients to age-matched controls with no history of cancer and no potentially interfering medication.

Study design

Healthy volunteers will be asked to donate 5 tubes of blood

Study burden and risks

Bruising at the side of the blood sampling

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 above 35 years

- Written informed consent

Exclusion criteria

- History of cancer
- Uuse of systemic immunosuppressive medication (eg. corticosteroids). Local use of corticosteroids (eg. topical or inhalation) is allowed.
- Fever 14 days before blood withdrawal
- Donated blood for the same program within the last 2 years
- Pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-04-2019
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	24-01-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	13-09-2019

Application type:	Amendment
Review commission:	METC NedMec

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	NL66828.031.18