

Determination of reference values: numbers, repertoire and products of leukocytes in immunological healthy elderly

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Generation of (age-dependent) reference values **of leukocytes and their subtypes and of their products, as well as analysis of (age-dependent) IG / TR repertoire. In order to be able to distinguish the age-dependent effects from effects caused by...

Ethical review	Approved WMO
Status	Pending
Health condition type	Leukaemias
Study type	Observational invasive

Summary

ID

NL-OMON50827

Source

ToetsingOnline

Brief title

Analysis of white blood cells in immunological healthy elderly

Condition

- Leukaemias
- Immune disorders NEC
- Ancillary infectious topics

Synonym

reference values

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: leukocytes, reference values

Outcome measures

Primary outcome

Insight in age-dependent distribution of leukocytes (subtypes), their IG/TR repertoire and their production of antibodies and cytokines.

Secondary outcome

Use of results for correct (and age-dependent) interpretation of abnormal values **in certain patient groups (such as e.g. patients with chronic lymphocytic leukemia, autoimmune diseases, etc.).

Study description

Background summary

Peripheral blood leukocytes consist of different types of cells, namely monocytes, granulocytes, B-lymphocytes and T-lymphocytes. The B and T lymphocytes can be further differentiated into various subtypes, based on protein markers on the cells, which differ in function and/or activation status. At the membrane of B and T lymphocytes molecules are present that can specifically recognize antigens. These are called resp. immunoglobulin (IG) and T cell receptor (TR) molecules. Each B or T lymphocyte basically has a unique IG or TR molecule.

All IG and TR molecules together provide a broad, so-called polyclonal, repertoire of antigen-specific receptors. It is known that infections, especially viral infections, can cause changes in numbers of B and T lymphocytes (subtypes) and in the IG/TR repertoire. It is also clear from literature that the relative distribution of the various subtypes of B and T lymphocytes can differ depending on age. It is also known that in older

individuals (defined as >65 years) a narrowing of the repertoire can occur, whereby even clones of B or T lymphocytes can be detected. However, for example, reference values **for the current, improved and more informative phenotyping protocols for B and T lymphocytes and their subtypes and for their products (antibodies, cytokines) are lacking. There is also insufficient detailed insight into the age-dependent changes in the IG / TR repertoire.

Such testing of reference values in elderly, healthy individuals is essential for two reasons:

1. insight into the age-dependent distribution of (subtypes of) leukocytes, their IG / TR repertoire and their production of antibodies and cytokines;
2. use for correct (and age-dependent) interpretation of deviating values **in certain patient groups (such as patients with chronic lymphocytic leukemia, autoimmune diseases, etc.).

Study objective

Generation of (age-dependent) reference values **of leukocytes and their subtypes and of their products, as well as analysis of (age-dependent) IG / TR repertoire. In order to be able to distinguish the age-dependent effects from effects caused by viral infections, it is important to know the specific immune response of healthy persons to viral infections in particular.

Study design

Prospective, observational study

Study burden and risks

This study has a minimal burden on the participant and there are no risks involved

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

- Immunological healthy elderly (without immunological history)
- No use of immunosuppressive drugs
- Age >50 years
- Signed informed consent

Exclusion criteria

- medical immunological history
- diagnosis of diabetes, cardiovascular disease, leukemia/lymphoma, malignancies, systemic auto-immune diseases/rheumatoid disease
- use of immunosuppressive drugs
- no signed informed consent

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 15-12-2021
Enrollment: 200
Type: Anticipated

Ethics review

Approved WMO
Date: 18-11-2021
Application type: First submission
Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL78020.078.21