

Age-matched reference values for naive and memory lymphocyte subpopulations in children

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Determining reference values for lymphocyte subpopulations in children

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|------------------------------|---------------------|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Other condition |
| Study type | Interventional |

Summary

ID

NL-OMON32941

Source

ToetsingOnline

Brief title

Age-matched reference values lymphocyte subpopulations

Condition

- Other condition

Synonym

reference values

Health condition

referentiewaarden bepaling

Research involving

Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis

Source(s) of monetary or material Support: Onderzoekspotje voor arts-assistenten JBZ

Intervention

Keyword: Children, Immunology, Lymphocyte subpopulations

Outcome measures

Primary outcome

Absolute and relative numbers of T-lymphocytes, B-lymphocytes, NK-cells, helper-T- and cytotoxic-T-lymphocytes, as well as absolute and relative numbers of naïve B-lymphocytes, IgM-memory B-lymphocytes, switched-memory B-lymphocytes, naïve and effector helper-T and cytotoxic-T-lymphocytes and central or effector memory helper-T and cytotoxic-T lymphocytes.

Secondary outcome

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Study description

Background summary

Summary of the study: Age-matched reference values for lymphocyte subpopulations in children

Immunophenotyping is an important tool in the diagnosis of immunological and haematological diseases. Age-matched reference values have been determined for the major lymphocyte populations (B-, T-, helper-T- and cytotoxic-T-lymphocytes and NK-cells), but are unavailable at present for subpopulations like naïve and memory cells, which are of special interest in a maturing immune system. Also, in specific immunological diseases immunophenotyping results are used for categorisation of patients and sometimes even for prognostic estimates. For this study we are determining reference values for B- and T-lymphocyte subpopulations. Therefore we include healthy patients in different age groups. EDTA-blood of these patients will be used for immunophenotyping with monoclonal

antibodies by flowcytometry. We will determine absolute and relative numbers of T-lymphocytes, B-lymphocytes, NK-cells, helper-T- and cytotoxic-T-lymphocytes. As well as absolute and relative numbers of naïve B-lymphocytes, IgM-memory B-lymphocytes, switched-memory B-lymphocytes, naïve and effector helper-T and cytotoxic-T-lymphocytes and central or effector memory helper-T and cytotoxic-T lymphocytes.

Summary of amendment 1

The monoclonal antibodies used in this study are adjusted for recent literature at actual start of the study.

Summary of amendment 2

Because it is difficult to include enough patients below two years of age, we will ask parents permission for a sole venapuncture, or a blood sample from heel or finger. A maximum of 35 children will be included according to the procedure described in this amendment.

Study objective

Determining reference values for lymphocyte subpopulations in children

Study design

Cross-sectional study design

Intervention

One venapuncture or blood sample taken from the heel or finger.

Study burden and risks

A sole venapuncture or bloodsample taken from the heel or vinger in healthy children under 2 years of age after permission of the parents. The risks are minimal: maximum a bruise.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Healthy children under the age of two years

Exclusion criteria

- Ill or recent infection (last two weeks)
- Immunomodulating or suppressive therapy
- Immunological diseases

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-11-2009

Enrollment: 35

Type: Actual

Ethics review

Approved WMO

Date: 22-10-2009

Application type: First submission

Review commission: CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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

CCMO

ID

NL28948.000.09