Analysis of the differential effects of anti thymocyte globulin (ATG) on lymphocyte subsets in patients with severe aplastic anemia

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* To evaluate the in-vivo effects of standard treatment of ATG and cyclosporine on lymphocytes in patients with SAA.* To evaluate persistence and binding capacity of circulating ATG derived antibodies in patients with SAA after treatment.* To...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Anaemias nonhaemolytic and marrow depression
Study type	Observational invasive

Summary

ID

NL-OMON42742

Source
ToetsingOnline

Brief title
ATG effects in Aplastic Anemia

Condition

- Anaemias nonhaemolytic and marrow depression

Synonym
severe aplastic anemia; acquired aplastic anemia

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

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

Intervention

Keyword: aplastic anemia, ATG (anti thymocyte globulin)

Outcome measures

Primary outcome

Number and phenotype of circulating lymphocytes before, during and after

treatment with ATG

Secondary outcome

Persistence and binding capacity of ATG derived antibodies

Study description

Background summary

Acquired severe aplastic anemia (SAA) is a rare, immune-mediated disease (incidence 2-3/million/year) characterized by a pancytopenia and an aplastic bone marrow. Immune suppressive treatment with Anti Thymocyte Globulin (ATG) combined with cyclosporine can induce responses up to six months after treatment. Although it was hypothesized that the working mechanism of ATG in SAA is based on its direct lympholytic effect on T cells, the ATG with the strongest anti T cell effect (Thymoglobulin) is less effective in SAA than the less T cell suppressive ATG forms (Lymphoglobulin and ATGAM). In order to find out whether direct effects of ATG on different subclasses of lymphocytes can explain the working mechanism of ATG in patients with SAA, an in-depth analysis will be done of circulating and bone marrow lymphocytes before, during and after treatment with ATG and levels and binding capacity of circulating ATG derived antibodies will be measured in SAA patients receiving standard treatment with ATG and cyclosporine.

Study objective

* To evaluate the in-vivo effects of standard treatment of ATG and cyclosporine on lymphocytes in patients with SAA.
* To evaluate persistence and binding capacity of circulating ATG derived antibodies in patients with SAA after treatment.
* To compare these ATG effects on lymphocytes between SAA patients who do and

who do not respond to treatment with ATG

Study design

This is an observational study in which extra blood will be drawn for study purposes. One extra bone marrow will be done at two months after start of the treatment. The immunosuppressive treatment (IST) is regular care based on national Dutch guidelines.

Study burden and risks

Extra blood will be taken during regular blood examinations (in total 270 ml extra, divided over 6 time points in a 8 week period). One extra bone marrow examination will be done (30 ml)

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 18 years or older
- Acquired aplastic anemia based on diagnosis criteria of the Dutch Guidelines for diagnosis and treatment of adult aplastic anemia
- Planned treatment with ATG

Exclusion criteria

- Severe psychological disturbances.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-01-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL54168.058.15