Effect of three B-cell inhibitors: rituximab, alemtuzumab and bortezomib on anti-A and/or anti-B titer kinetics.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haematological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON39959

Source
ToetsingOnline

Brief title
anti-A/B titers

Condition

- Haematological disorders NEC
- Renal disorders (excl nephropathies)

Synonym
kidneytransplant

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: anti-A titers, anti-B titers, desensitization, kidney transplant

Outcome measures

Primary outcome

The dynamics of the anti A/B titer in time of three different B cell-inhibitors

(rituximab, bortezomib, alemtuzumab).

Secondary outcome

effect of blood transfusions on the anti A?B titers.

Study description

Background summary

Because of a shortage of cadaveric donororgans for transplantation, nowadays more kidneys from living donors are used. Since recent years also ABO-incompatible transplantations are performed. The anti A or B antibodies in the recipient in this case could result in hyperacute rejection. This involves B-cells that produce the antibodies and might fulfill other immunogenic roles. To prevent rejection, desensitisation procedures are performed, which are done by plasmapheresis, IVIG, ATG and antigen-specific immune absorption in combination with immune suprresive drugs. In the LUMC ABO-incompatible kidneytransplants are performed since 2010 and patients are pretreated with B-cell inhibitors after which remaining anti A/N antibodies are removed bij plasma exchange and/or immune absoprtion procedures. Three different B-cell inhibitors are used. Thus far it is unclear which drug results in optimal decrease of anti A/B antibodies.

Study objective

The goal of this study is to find out which B-cell inhibitor results in the best reduction of anti A/B antibody levels at which time interval, to make the best choice for a particcular drug in the desensitization treatment in patients receiving an ABO-incompatible transplant.

Study design

In patients that are treated with one of the three B-cell inhibitors

(rituximab, bortezomib, alemtuzumab) with or without chemotherapy, an EDTA tube of blood is withdrawn at start of this treatment and before every new cycle of treatment (weekly up to 4-weekly till a maximum of 8 times). The bllod will be taken in addition to regular blood test. The serum is frozen on the bloodtrasfusion department and at later timepoints the anti A/B levels of the collected samples are measured. This will result in different kinetica of anti A/B titers in time of the three different drugs.

Study burden and risks

The burden for the patient participating in this study will be an extra 8 ml bloodwithdrawal during a regular withdrawal (patients do not have to undergo an extra venapuncture). This extra blood tube will be collecte up to a maximum of 8 times in a period of 24-32 weekstime (dependent on their treatment scheme). This will not induce a risk for the patient. The induction of anemia is thought to be unrelevant to the patient.

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 yr
patients should be competent
have blood group A,B or O
will receive treatment with rituximab, bortezomib, alemtuzumab (prescribed by their hematologist)

Exclusion criteria

blood group AB
having a low antiA/B titer < 1:8
treatment with IVIG or plasma in the past three months

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2013
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	19-02-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL41978.058.12