C1-inhibitor improves recovery of red blood cell transfusion in patients suffering from autoimmune hemolytic anemia – an open-labeled pilot trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22958

Source
Nationaal Trial Register

Brief title
C1-inh in AIHA

Health condition

Autoimmune Hemolytic Anemia

Sponsors and support

Primary sponsor: Academic Medical Center (AMC)
Source(s) of monetary or material Support: Academic Medical Center (AMC)

Intervention

Outcome measures

Primary outcome

• improvement of recovery of RBC transfusion,

• inhibition of complement activation and deposition on RBC via the classical pathway of complement,
• safety

Secondary outcome

• Attenuates the pro-inflammatory response in AIHA
• Affects the response to the basic treatment targeting autoantibody production

Study description

Background summary

This is a prospective, multicenter, national open label study to test the efficacy of C1-inh to improve the efficacy of RBC transfusion in patients with AIHA

Study objective

Because C1-inh is an efficient inhibitor of the classical pathway of complement with an excellent safety profile we hypothesized that C1-inh might inhibit autoantibody mediated destruction of donor RBS in order to improve efficacy of RBC transfusion.

Study design

8 timepoints

Intervention

C1 inhibitor (Cinryze)

Contacts

Public
Amsterdam UMC, location AMC
Edith van Dijkman

+31641360674
Scientific
Amsterdam UMC, location AMC
Edith van Dijkman

+31641360674

Eligibility criteria

Inclusion criteria

• Positive (≥1+) monospecific antiglobulin test for C3b and/or C3d with/without positivity for IgM OR strongly positive (≥3+) monospecific antiglobulin test for C3b and/or C3d with positivity for IgG
• Indication for a transfusion with at least 2 red packed cell concentrates based on the clinical assessment by the hematologist in charge
• Hemoglobin value at least < 5 mmol/L (8 g/dl) with/without clinical symptoms
• Clinical signs of hemolysis: not-detectable haptoglobin (mandatory) and increased lactate dehydrogenase (LDH) eventually combined with hyperbilirubinemia (increased direct and/or indirect bilirubin), lactate.
• Age ≥ 18 years
• Written informed consent
• Women of child bearing potential must have had a negative serum pregnancy test 7 days prior to the start of study drug

Exclusion criteria

• History of arterial and/or venous thromboembolic events in the absence of an actual treatment with Vitamin K-antagonists
• Concomitant use of therapeutic doses of heparin
• Female patients who are pregnant or breast feeding or adults of reproductive potential who are not using effective birth control methods. If barrier contraceptives are being used, these must be continued throughout the trial by both sexes. Oral contraceptives only are not acceptable.
• Patients with known HIV seropositivity or chronic active hepatitis
• Patients who have any severe and/or uncontrolled medical condition or other conditions that could affect their participation in the study such as:
– cerebrovascular accidents ≤ 6 months before study drug start
– uncontrolled hypertension

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2012
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	14-11-2019
Application type:	First submission

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
NTR-new	NL8164
Other	METC AMC : METC 2012_266

Study results