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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22958

Bron
Nationaal Trial Register

Verkorte titel
C1-inh in AIHA

Aandoening

Autoimmune Hemolytic Anemia

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)
Overige ondersteuning: Academic Medical Center (AMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

8 timepoints

Onderzoeksproduct en/of interventie

C1 inhibitor (Cinryze)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2012
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	14-11-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8164
Ander register	METC AMC : METC 2012_266

Resultaten