Sickle Cell Disease: Targeting Alloantibody formation Reduction (STAR) - Risk factors for alloantibody formation

Published: 31-07-2014
Last updated: 24-04-2024

In this study the cumulative incidence and the clinical and immunogenetic determinants of allo-antibody formation in SCD patients in response to RBC transfusion will be evaluated.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haemoglobinopathies
Study type	Observational invasive

Summary

ID

NL-OMON41526

Source
ToetsingOnline

Brief title
STAR

Condition

- Haemoglobinopathies

Synonym
Alloimmunisation in blood transfusion recipients; Formation of antibodies against foreign red blood cells after blood transfusion

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Academisch Medisch Centrum;Sanquin Bloedvoorziening

Intervention

Keyword: Alloantibody, Alloimmunisation, Risk factors, Sickle Cell Disease

Outcome measures

Primary outcome

The primary study parameters are:

- Immunogenetic determinants that could determine alloimmunisation; Variations in the gene cluster encoding the Fc-gamma receptors and the SIRP-alpha receptor (Signal Regulatory Protein-alpha).

- Clinical determinants that could determine alloimmunisation such as gender, SCD genotype, geographic origin, age, age of first transfusion and number of transfusions.

The main study outcome is the cumulative incidence of allo-antibody formation in response to RBC transfusion.

Secondary outcome

N/A

Study description

Background summary

Allo-antibody formation is a frequent complication of transfusion. The risk of alloimmunization varies from 1-8% in incidental transfusion recipients, to >40% in patients receiving transfusion on a regular base. A population that frequently receives transfusions is formed by patients with sickle cell disease (SCD), a hereditary hemoglobinopathy characterized by chronic anemia. These patients thus have an increased risk of developing allo-antibodies.
Red Blood Cell alloimmunization may jeopardize optimal transfusion support in affected patients, poses these patients at risk for hemolytic transfusion

reactions, increases the costs of transfusion and forms a logistic challenge for the blood supply system due to the need of extended blood type matching. Both genetic and clinical factors are presumed to be risk factors for alloimmunization. Genetic variation in the Fc-gamma-receptor was demonstrated to influence antibody formation in patients with idiopathic thrombocytopenic purpura.
Identifying risk factors will help in the identification of patients at high risk of RBC alloimmunization. RBC alloimmunization may than be prevented by special preventive measures such as a more extended matching strategies.

Study objective

In this study the cumulative incidence and the clinical and immunogenetic determinants of allo-antibody formation in SCD patients in response to RBC transfusion will be evaluated.

Study design

This is a national, multicenter observational cohort study that will include SCD patients from three different hospitals.

Study burden and risks

The risks of participation are expected to be negligible. This is a non-therapeutic study as the participating patients themselves will not benefit from participating in this study. The burden is comparable with the burden that patients with this disease experience in daily life with standard medical care as the one-time only acquisition of a blood sample will be combined with routine follow-up blood sampling.

Our research question is group related. As many SCD patients start receiving transfusions in the first years of life, it is important to include children in our study. Also, transfusion protocols have changed in the last years and presently RBC units are matched more extensively than before. It is important to include the effects of this strategy in our analyses. These effects can only be addressed in children that have been transfused exclusively with extensively matched RBC units.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9

Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Sickle Cell Disease (phenotypes HbSS, HbSC, HbS*+, HbS*0 or HbSE)
- History of at least 1 RBC transfusion in one of the participating centers

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-11-2014
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	31-07-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL43029.018.13