Measuring survival of transfused red blood cells in patients with Sickle cell disease and β-Thalassemia: A Biotin Label approach

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25329

Source
Nationaal Trial Register

Brief title
Mr. STABLE

Health condition

Sickle cell disease & β-thalassemia

Sponsors and support

Primary sponsor: Amsterdam UMC - location AMC
Source(s) of monetary or material Support: Sanquin Blood Supply

Intervention

Outcome measures

Primary outcome

The primary outcome is the survival of transfused RBCs in patients with sickle cell disease

and β-thalassemia.

Secondary outcome

Inter patient study parameters will focus on the effects of the transfusion. The main parameters will be:
• Inflammatory/immunomodulatory response on transfused RBCs.
• Influence of previous responder status on RBC survival.
• Antibody formation to the biotin label.

Intra patient study parameters will focus on the effect of matching of the RBC units. Both units will be matched differentially.
The main parameters will be:
• The recovery, short term and long term survival of both RBC units.
• The (immediate and late) host immune response to both RBC units by measuring effect on expression of markers of clearance and inflammation as well as transcriptome analysis.

Study description

Background summary

Rationale: Red blood cell (RBC) transfusions are currently one of the most important therapeutic options for patients with sickle cell disease and β-thalassemia. Over the last years much research has been conducted to improve transfusion safety, especially focussing on antigen matching to prevent alloimmunization. However, the fate of transfused RBC in these patients is largely unknown. Until now it has been difficult to track RBCs once transfused. A recently developed method (biotinylation of RBC units) allows a robust analysis of survival and clearance of the transfused RBCs. Insight in these phenomena may help to elucidate individual variation of RBC survival and behaviour in these patients.
Our objective is to assess the survival of transfused red blood cells (RBC) in patients with sickle cell disease and β-thalassemia by use of biotin labeled RBCs

Study objective

Survival of transfused erythrocytes will depent on donor and unit characteristics

Study design

T-1: Analysis of blood group genes
T0: Pre transfusion
T1: 10 minutes after transfusion
T2: 2 hours after transfusion
T3: 1 day after transfusion
T4: 10-12 days after transfusion

T5: 4-6 weeks after transfusion

Contacts

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Eligibility criteria

Inclusion criteria

• Patient with either sickle cell disease (HbSS/HbSβ0/HbSC/HbSβ+) or β-thalassemia (major or transfusion dependent thalassemia intermedia)
• Currently on chronic transfusion program.
• >18 years of age

Exclusion criteria

No venous access for blood drawings

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-05-2019
Enrollment:	15
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	16-05-2019
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	NL7734
Other	METC AMC : 2018_299

Study results