Preventive extended red blood cell antigen matching: when and how?

Published: 25-09-2007
Last updated: 08-05-2024

To reduce the incidence of alloimmunization through preventive donor matching for the clinically relevant red blood cell antigens.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31145

Source
ToetsingOnline

Brief title
Match study

Condition

- Other condition

Synonym
No specific disease

Health condition

Aandoeningen die als ondersteuning van de therapie/ingreep bloedtransfusie vereisen

Research involving
Human

Sponsors and support

Primary sponsor: Sanquin Bloedbank
Source(s) of monetary or material Support: Sanquin

Intervention

Keyword: Extended matching, RBC transfusion

Outcome measures

Primary outcome

Incidence of alloimmunization in transfusion patients through preventive donor matching for clinically relevant antibodies compared to standard matching in patients stratified for high and random risk alloimmunization

Secondary outcome

1. Cost-analysis for current serologic screen and match strategy compared to preventive matching strategy in the 2 strata of patients

2. Investigate transfusion and/or other medical treatment delay in case of RBC alloimmunization

3. Obtain data on clinical and genetic factors associated with RBC alloimmunization

Study description

Background summary

Preventive extended red blood cell antigen matching: when and how?
Red blood cell (RBC) alloimmunization after blood transfusions results from the genetic disparity between patient and donor. After multiple transfusions, up to 60% of patients will develop alloantibodies. In more than 80% of cases, these antibodies are directed against the clinically relevant C-,c-,E-,e-,K-,Fya-,Jka-, and S antigens. This high immunization rate led to the policy to prophylactically match RBC transfusions for Rh-C,-c,-E,-e and K antigens for high risk hematological patients and females in their (pre)reproductive age. For all other patients, red blood cell transfusions are only ABO-D compatible. When antibodies are detected in case of a subsequent transfusion event, RBCs also compatible with these antibodies are selected. This requires extensive and time consuming manual assays in a reference

laboratory, which can cause delay of treatment. Furthermore, for patients with multiple antibodies, compatible blood may not be readily available.
A longer life expectancy is associated with an increased probability of repeat surgery or diseases, which in turn can increase the chance of multiple transfusion events. Except of particular populations, patients at risk for RBC alloimmunization and the costs associated with it are unknown. The development of micro-array and bead technology will inevitably lead to the possibility of extensive RBC genotyping of donors. Prior to the availability of this technology, we will identify patients for whom preventive matching is most efficient and know the costs associated with RBC alloimmunization and transfusion support.

Study objective

To reduce the incidence of alloimmunization through preventive donor matching for the clinically relevant red blood cell antigens.

Study design

Patients included in the study will be stratified into two strata. The stratum is defined by transfusion history and the presence (high risk) or absence (random risk) of antibodies. In both strata, patients are randomly assigned to receive standard RBC or extended matched RBC transfusions. Detection of antibody formation will take place during 3 fixed time points.

Intervention

Standard ABO-D compatible versus extended (C,c,E,e,K,Fya,Jka and S) compatible red blood cell products. Both have equal standard product-specifications

Study burden and risks

Although red cell transfusions are considered to be safe, adverse transfusion reactions may occur. Not only are all transfusion reactions registered for the purpose of this study, but they are also reported to the *TRIP Landelijk Hemovigilantie Bureau* and handled according to the CBO consensus as is routinely done in current medical practice. The study intervention could theoretically lead to unintended transfusion delays. In case of clinical consequences due to delays, the transfusion committee of the local hospital will be informed.

Contacts

Public

Sanquin Bloedbank

Plesmanlaan 1a
2333 BZ Leiden
NL
Scientific
Sanquin Bloedbank

Plesmanlaan 1a
2333 BZ Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The general transfusion population >18 years requiring an elective RBC transfusion

Exclusion criteria

Patients younger than 18 years
Patients with an a priori indication for matched transfusions (congenital hemolytic anemia*s, immune hemolytic anaemia, females of (pre-) childbearing age)
Patients with a positive DAT
Patients who, based on the local pre-operative blood-ordering list, require more than 4 RBC units during surgery.
Incapacitated subjects or patients who cannot understand the information.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-06-2008
Enrollment:	1120
Type:	Actual

Ethics review

Approved WMO Date:	25-09-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL17890.098.07