Age of Blood Evaluation, resuscitation in the critically ill

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ABLE study:To determine whether red cells stored less than 8 days reduce the 90-day all-cause mortality with 5% in critically ill ICU patients in need of a red cell transfusion compared to ICU patients who receive "older" red cells stored...

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

Summary

ID

NL-OMON39346

Source
ToetsingOnline

Brief title
ABLE

Condition

- Other condition

Synonym
90 day mortality, mortality rate in ICU, transfusion reaction

Health condition

overall clinical outcome in ICU patients

Research involving
Human

Sponsors and support

Primary sponsor: Sanquin Bloedbank
Source(s) of monetary or material Support: Sanquin bloedvoorziening & ABLE study group Canada

Intervention

Keyword: 90 day all cause mortality, ICU patients, RBC transfusion, Storage time

Outcome measures

Primary outcome

Our primary outcome in the ABLE study is the 90 day mortality. We hope to

achieve an absolute risk reduction in the 90 day mortality of 5%.

Additional endpoints for the VuMC substudy:

Capillary density, Mean flow index, the proportion of perfused vessels (PPV),

perfused vessel density (PVD), tissue oxygenatie.

Secondary outcome

Secondary endpoints ABLE study

1) In hospital mortality, mortality during ICU admittance, mortality at 28 days

and after 6 months.

2) MODS and the severity of organ failure determined by the MODS score

3) nosocomial infections

4) Length of stay in the ICU

5) Lenght of hospital stay

6) transfusion reactions

Study description

Background summary

Donated red cells in the Netherlands can be stored up to 35 days. However some laboratory and clinical data suggest that giving older units could be less effective and detrimental. Loss of deformability and 2,3 DGP, the release of cytokines and the release of other mediators are reported.
Anemia is a common problem on the ICU. 95% of all American ICU patients develops anemia in the first 3 days of admittance; 40-45% of all ICU patients receives at least one red cell transfusion during the ICU admittance.
An extended RCT evaluating the consequences of red cell storage time has never been done. In the ABLE study we wish to compare the effect of red cells younger then 8 days with red cells tranfused according to standard procedure.

Substudie in het VUmc: the role of storage time of transfused red blood cells on microcirculation and tissue oxygenation in critically ill patients:

In literature side-effects of red blood cell (RBC) transfusions are widely described. It is thought that there might be an important role for the microcirculation in detrimental effects on clinical outcome after RBC transfusion. During storage RBC undergo biochemical changes which lead to the deformation of red cells and which can cause impairing of the microcirculation because the RBC have to migrate through the smallest capillairies. Various studies intended to evaluate the direct impact of RBC transfusion on microcirculation, but they don't show unequivocal results. Therefore we ould like to determine the effects of storage time of RBC's on microcirculation using SDF imaging.
Futhermore we question whether the objectiveof RBC transfusion, to maintain adequate tissue hemoglobin oxygenation is accomplished independent of the storage time of RBC's. Therefore we will evaluate the tissue hemoglobin oxygenation after transfusion of standard or fresh RBCs using near infrared spectometry (NIRS).

Study objective

ABLE study:
To determine whether red cells stored less than 8 days reduce the 90-day all-cause mortality with 5% in critically ill ICU patients in need of a red cell transfusion compared to ICU patients who receive "older" red cells stored 2 to 35 days.

Substudy in the VUmc: the role of storage time of transfused red blood cells on microcirculation and tissue oxygenation in critically ill patients:

The aim is to gain more insight in the effect of storage time of RBCs on microcirculation and tissue hemoglobin oxygenation in critically ill patients.

Study design

The ABLE study is a double-blind, multicenter, randomized clinical trial. The study will run in Canada, France, Great Britain and the Netherlands. We have chosen to study a heterogeneous group of critically ill patients who receive at least one red cell unit throughout the critical care phase of their illness using pre-storage leuko-reduced cells. Patients will be randomized to receive either 1) standard issue red cells (storage: 2 to 35 days) or 2) red cells stored 2 to 7 days. We plan to compare 90-day all-cause mortality, other mortality rates (28-day, ICU, hospital and 6-month mortality), rates and severity of organ failure, rates of serious nosocomial infections, length of time receiving organ support such as mechanical ventilation, and length of ICU and hospital stay.

Substudy in the VUmc: the role of storage time of transfused red blood cells on microcirculation and tissue oxygenation in critically ill patients:
Sublingual and microcirculatory density and perfusion will be monitored using non-invasive Side Stream Dark Field (SDF) imaging in 40 patients who are included in the ABLE study on 5 different time points (before transfusion of a RBC unit, immediately following transfusion, 1 hour after transfusion, 6 hours after transfusion, 24 hours after transfusion)

To determine the relation between tissue hemoglobin oxygenation and storage time of RBCs tissue hemoglobin oxygenation will be measured using near-infrared spectroscopy (NIRS) using the Equanox-7600. Tissue hemoglobin oxygenation will be measured simultaneously with the SDF measurements, by placing an adhesive strip as a sensor on the patient's forehead.

Intervention

The intervention of our interest is the transfusion of red cells with a reduced maximal storage time. We will randomize between transfusing red cells stored 2 to 7 days and red cells stored according to standard procedure; 2 - 35 days.

Study burden and risks

To our knowledge, the standard care in regards to red cell transfusion used in this study does not involve any additional risk. Our experimental arm receives *fresher* red blood cells (2- 8 days) while the control arm receives standard

care (red cells from 2 -35 days of age). So our *experimental* intervention is in fact a subscribed limitation within the standard practice. Red cells in the "fresher" arm are processed and checked for pathogens according to the standard protocol. There is no known direct benefit in participating in this study. Participants receiving younger blood may respond better to the red cell transfusion.

VuMC substudy:
The burden associated with participation in this study is limited. Patients will be subjected to non-invasive SDF imaging under the tongue together with NIRS measurements on the forehead at five different time points.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) The need of a first red cell unit transfusion in the first 7 days of ICU admittance (or in the emergency department after admission to the ICU was requested by an intensivist),
2) an anticipated length of invasive and/or non-invasive mechanical ventilation of at least 48 hours once enrolled, as estimated by the attending physician.
3) age >18 years

Exclusion criteria

Exclusion criteria ABLE:
- Age below 18
- Suspection (written or otherwise) of a previous red cell transfusion during the current admitance
- Preexisting terminal illness with a life expectancy < 3 months
- Patients who undergo routine elective (cardiothoracic) surgery during the same hospitalisation
- Patients who have treatment restrictions other then a DNR at the time of randomization
- Patients who are declared braindead
- Patients who have moral or religious reasons to refuse a red cell transfusion
- Patients who received autologous blood
- Patients who are included in an other study
- Patients whose physician refuses to include him/her
- Patients who have previously participated in the ABLE study
- Patients who received more then one unit of uncross-matched blood
- When supplying the right randomised red cell unit causes logistical problems

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-01-2012
Enrollment:	450
Type:	Actual

Ethics review

Approved WMO Date:	01-08-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-05-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-05-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	18-03-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	31-05-2013

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	09-07-2013
Application type:	Amendment
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
ISRCTN	ISRCTN44878718
CCMO	NL35068.098.11