The efficacy of blood transfusions to improve microcirculatory oxygen delivery in anemic patients.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON30782

Source
ToetsingOnline

Brief title
The efficacy of blood transfusions in anemic patients.

Condition

- Other condition
- Red blood cell disorders
- Haematopoietic neoplasms (excl leukaemias and lymphomas)

Synonym
acute myeloid leukemia. leukemia

Health condition

bloed doorstroming in de microcirculatie

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anemia, blood transfusions, microcirculation

Outcome measures

Primary outcome

Noninvasive measurements:

Sidestream Dark-Field (SDF) Imaging-microcirculation quantification

Fibre spectrophotometry and laser Doppler flowmetry (O2C)

Invasive measurements:

Blood sample

Secondary outcome

N.v.t.

Study description

Background summary

The primary goal of giving blood transfusions for correcting anemia, is to provide oxygen rich blood to the microcirculation where it can give oxygen to the tissue cells. There is little evidence, however, that shows that this goal is actually achieved in anemic patients. In fact in certain disease states there is evidence that blood transfusion may even have deleterious effects. Even though systemic variables of hematocrit and hemoglobin concentrations rise following transfusion, the efficacy of transfused blood to actually reach the microcirculation and oxygenate the tissues may not be achieved. Experimental studies conducted by us and others have identified various factors associated

with deterioration of red blood cell (RBC) function during storage and transfusion which impair its ability to provide oxygen to the microcirculation. The main purpose of this project is to investigate the conditions under which blood transfusions are successful in promoting microcirculatory circulation and oxygenation in anemic patients. In this project we wish to apply our state of the art optical spectroscopic techniques to patients undergoing blood transfusion to asses the success of blood transfusion in supplying the microcirculation with oxygen-rich blood. We will also measure parameters known to affect RBC function related to the transfused blood as well as parameters relating to the condition of the host. Since the pathogenic nature of the host and cause of anemia can impact the ability of transfused blood to reach the circulation we have chosen to investigate 2 patient categories where blood transfusions are needed. These include anemic patients and patients who are under chemotherapy treatment.

The hypotheses we wish to test in this project are as follows:
1. Transfusion of RBCs in anemic patients causes an improvement in microcirculatory blood flow and oxygen delivery.
2. Storage of RBCs impairs the ability of transfused cells to supply the microcirculation with oxygen rich blood.
3. Underlying disease can affect the microcirculation and/or the transfused blood, impairing its ability to oxygenate the microcirculation.
4. Nitric oxide and its products altered during storage and disease are the main cause of RBC and microcirculation dysfunction impairing proper transport of transfused cells to the microcirculation.

Study objective

The main purpose of this project is to investigate the conditions under which blood transfusions are successful in promoting microcirculatory circulation and oxygenation in anemic patients. In this project we wish to apply our state of the art optical spectroscopic techniques to patients undergoing blood transfusion to asses the success of blood transfusion in supplying the microcirculation with oxygen-rich blood. We will also measure parameters known to affect RBC function related to the transfused blood as well as parameters relating to the condition of the host. Since the pathogenic nature of the host and cause of anemia can impact the ability of transfused blood to reach the circulation we have chosen to investigate 2 patient categories where blood transfusions are needed. These include anemic patients and patients who are under chemotherapy treatment.

Study design

This is observational research with invasive and non-invasive measurements. The measurements we are going to carry out can be classified in two groups. The first group of measurements is going to be performed by using in-vivo clinical

techniques to investigate the microcirculatory perfusion and oxygen availability. For that purpose we are going to use SDF and O2C techniques. A second group of measurements will be with samples collected from the patients and blood bags in certain time points. This group of measurements includes full blood count, blood gases (including lactate, systemic hemoglobin), blood chemistry, RPC as an inflammatory marker, hematocrit viscosity, RBC morphologic test (MCV, MCH, MCHC), strong ion difference, nitric oxide products (nitrite and nitrate), 2,3-DPG, ATP, eNOS, and RBC deformability and aggregability. For these measurements 3 tubes of blood (2 times 15 ml) will be taken. Collected samples will be immediately sent to the laboratory or rapidly cooled to below 4 degree Celsius. Patient characteristics, systemic parameters and the storage age of blood cells will be recorded at all time points.

Baseline measurements will be performed before the beginning of blood transfusion. The administration of blood transfusion needs 90 minutes in all groups. Second measurement will take place at 60 minutes after transfusion is completed.

Study burden and risks

N.v.t.

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. Anemic patients and patients who under chemotherapy treatment receiving blood transfusion
2. Approval from the physician that will be treating the patients
3. Informed consent from each participating patient
4. Patients older than 18 years
5. Transfusion of blood from different storage age (more than 1 week difference in the duration of storage)
6. Transfusion of blood from storage age less than 1 week and more than 4 weeks.

Exclusion criteria

1. Patients that did not sign an informed consent
2. Patients younger than 18 years

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	22-01-2007
Enrollment:	75
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission
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	NL16037.018.07