Relation between in vitro parameters of stored red blood cells and in vivo survival of these red blood cells after autologous transfusion

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To determine the relation between in vitro parameters of stored red blood cells and in vivo survival of these red blood cells after autologous transfusion. To identify the relationbetween the recipients immune response to stored autologous red cells...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON32650

Source ToetsingOnline

Brief title red cell survival after storge of autologous red cells

Condition

• Bone and joint therapeutic procedures

Synonym autologous transfusion in orthopedic surgery

Research involving

Human

Sponsors and support

Primary sponsor: ABTI

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Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: autologous red cell, red cell survival, storage lesion

Outcome measures

Primary outcome

functional red cell parameters PS exprssion, band 3 changes, red cell

vesiculation

Secondary outcome

na

Study description

Background summary

Many side effects of red blood cell transfusion have been described. They include iron-overload, as well as allo-and auto antibody formation against red cells. During storage, erythrocytes undergo complex structural and biochemical changes. It has been suggested that accelerated and/or aberrant forms of the physiological erythrocyte aging process underlie the red cell storage lesion. This storage lesion may contribute to side effects of transfusion as endothelial damage by release of internal erythrocyte constituents, (pro)inflammatory consequences, hampered microcirculation and oxygen delivery. Understanding the process that determines the fate of red blood cells after transfusion may contribute to the prevention of side effects after red blood cell transfusion. Physiological, age-dependent removal of erythrocytes is an efficient and well-regulated process, with controlled exposure of the molecules that determine recognition by the autoimmune system (senescent cell antigen on band 3, phosphatidylserine in the outer leaflet of the membrane, decreased CD47), resulting in binding of autologous IgG and phagocytosis by the reticulo-endothelial system [5, 16, 17]. A molecular picture of the pathways involved in this process (oxidative damage-induced, high-affinity binding of hemoglobin to band 3, activation of Ca2+-permeable channels, phosphorylation-controlled loss of metabolism and structure, degradation of band 3 and aggregation of band 3 fragments, vesicle formation) is gradually emerging [5], but precise data on the initial triggers and cross-talk between these pathways are lacking. In addition, it is becoming clear that the

erythrocyte contains a complex, functional set of regulatory systems that trigger erythrocyte removal after physiological or pathological injury such as osmotic shock, oxidative stress and/or energy depletion [17]. Modulation of these pathways becomes progressively lost during storage [4, 18], resulting in accelerated aging and fast (< 24 hours) removal of up to 30% of the transfused erythrocytes. Erythrocyte aging is associated with a selective increase of autoimmune epitope expression, and accelerated aging may be associated with increased vesiculation and expression of pathogenic epitopes on erythrocytes and their vesicles [19]. Frequent blood transfusions may lead to immunization and formation of alloantibodiesand other side effects..

Study objective

To determine the relation between in vitro parameters of stored red blood cells and in vivo survival of these red blood cells after autologous transfusion. To identify the relationbetween the recipients immune response to stored autologous red cells in comparison with allogeneic transfused red cells.

Study design

Patients of which autologous red cells are taken preoperatively will be included. Samples of the unit of autologous red cell and samples from patient taken before transfusion and samples post-transfusion during an interval of 8 hours after transfusion will be taken. Biochemical evaluation of parameters known to be associated with red cell damege (PS expression, badn 3 changes, red cell vesucluation will be tested. Results will be compared with the a historical control group of patient sin which allogeniec rd cells were transfused.

Study burden and risks

5 times addiotional blood sampling

Contacts

Public Selecteer

Postbus 9101 6500 Hb Nijmegen Nederland **Scientific** Selecteer

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Postbus 9101 6500 Hb Nijmegen Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

planned elective orthopaedic surgery included for autologous red cell donation in standard used procedure

Exclusion criteria

no autologous red cells available. foreseen additional allogenic red cell transfuison

Study design

Design

Study type:Observational non invasiveIntervention model:OtherAllocation:Non-randomized controlled trialMasking:Open (masking not used)Control:Active

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Primary purpose:

Basic science

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2008
Enrollment:	10
Туре:	Anticipated

Medical products/devices used

Registration:	
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Ethics review

Approved WMO	
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

No

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 CCMO ID NL26006.091.08