An In Vivo 24-Hour Recovery Study of Leukoreduced RBCs After Automated Separation of Whole Blood by the Reveos System and Storage With Non-DEHP Disposables.

Published: 30-04-2024
Last updated: 08-02-2025

To evaluate whether the RBCs derived from WB and processed with the Reveos system using the non-DEHP disposable sets meet the US criteria for 24-hour recovery after 42 days of storage.

Ethical review	Approved WMO
Status	Completed
Health condition type	Red blood cell disorders
Study type	Observational invasive

Summary

ID

NL-OMON56734

Source
ToetsingOnline

Brief title
HYBRID-study

Condition

- Red blood cell disorders

Synonym
Anemie

Research involving
Human

Sponsors and support

Primary sponsor: Terumo
Source(s) of monetary or material Support: Terumo BCT

Intervention

Keyword: Biotin, Non-DEHP blood bags, Red blood cell, Transfusion

Outcome measures

Primary outcome

To evaluate whether the RBCs derived from WB and processed with the Reveos system using the non-DEHP disposable sets meet the US criteria for 24-hour recovery after 42 days of storage.

Secondary outcome

Secondary objective: To ensure RBCs derived from WB and processed with the Reveos system using the non-DEHP disposable set meet the European Directorate for the Quality of Medicines; Health Care (EDQM) criteria for a transfusable RBC product.

Study description

Background summary

Poly-vinyl-chloride (PVC), a type of plastic, is commonly used in the medical industry to produce flexible products such as blood bags. To make PVC flexible, plasticizers are added, with di(2-ethylhexyl)phthalate (DEHP) being the most widely used plasticizer worldwide. DEHP has been used in medical devices, including blood bags, since 1955 due to its ability to preserve the quality of red blood cells during storage. Years ago, concerns about the toxic effects of DEHP on fertility were raised due to animal studies. Consequently, the European Union (EU) implemented bans on DEHP use in toys and cosmetics, and restrictions on its use in the food industry. More recently, the EU decided to ban DEHP plasticizers in medical equipment, including blood bags, with expected sun setting in 2030. Consequently, blood bag system manufacturers are now exploring

alternative plasticizers. Laboratory (pre-clinical) research using the Reveos Blood Bag Set shows comparable results to current "plastic" DEHP blood bags in terms of red blood cell quality. However, it is important to show that the red blood cells also function after being transfused into individuals. Beside the EU, the blood bags may also be used in the United States (US) after approval. Therefore, the maximum accepted shelf life will be tested according to the US directive (42 days of storage).

Study objective

To evaluate whether the RBCs derived from WB and processed with the Reveos system using the non-DEHP disposable sets meet the US criteria for 24-hour recovery after 42 days of storage.

Study design

This is a prospective, open-label study to evaluate WB derived RBCs processed using the Reveos system with an investigational non-DEPH disposable set (LR-EXT). This study will be conducted in one phase, addresses the main objective, which is to assess the autologous in vivo recovery of biotin labeled LR-RBCs derived from WB processed using the Reveos system and stored in PAGGSM for 42 days.

Intervention

Phase I: biotinylated RBCs stored for 35 days.
Phase II: biotinylated RBCs stored for 42 days.

Study burden and risks

Recently, it was shown that the use of biotin labelled RBCs for transfusion (METC protocol 2012-299) is safe in healthy volunteers. Transfusions will be prepared and transfused using the standard clinical protocols by Sanquin blood bank and the Amsterdam UMC, location AMC.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Inclusion criteria for participant selection:
1. Healthy volunteers
2. Age >= 18 years < 60 years
3. Normal health status as per Sanquin National Blood Bank criteria for healthy donors
4. Able to commit to the study schedule
5. Participants of childbearing potential must agree to use a medically acceptable method of contraception throughout of the study
6. Participants of childbearing potential must be willing to take a pregnancy test prior to WB donation
7. Signed and dated informed consent form within 30 days of the Day 0 visit

Exclusion criteria

Exclusion criteria for participant selection:
1. Pregnant or nursing females
2. Serum ferritin <12 ng/mL
3. Has previously completed this study with evaluable data points
4. Participation currently, or within the past 30 days, in another investigational trial that would potentially interfere with the analysis of this investigation (e.g. pharmaceutical)
5. Participants who are deferred from volunteer community donations as per

Sanquin National Blood Bank criteria for healthy donors
6. As determined by the Investigator a. Has been diagnosed with a blood disorder(s) affecting RBC characteristics (e.g. G6PD deficiency). b. Reported history of RBC autoantibodies/autoimmune hemolytic anemia, RBC alloantibodies c. Clinically significant acute or chronic disease d. Reported history or known hypersensitivity to biotin and iodine e. Treatment with any medication as specified in site deferral list f. Current drug use g. Currently abusing alcohol. Alcohol abuse is defined for men, consuming more than 4 drinks on any day or more than 14 drinks per week and for women, consuming more than 3 drinks on any day or more than 7 drinks per week
7. Previously transfused with RBCs within the last 120 days
8. A positive biotin antibody test if they have received any biotin labeled blood products in the past
9. Blood loss of more than 500 mL < 3 months, including blood donation
10. Other unspecified reasons that, in the opinion of the investigator make the subject unsuitable for enrollment

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	17-05-2024
Enrollment:	26
Type:	Actual

Medical products/devices used

Generic name:	non-DEHP Reveos disposable (LR-EXT)
Registration:	No

Ethics review

Approved WMO Date:	30-04-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-08-2024
Application type:	Amendment
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	NL84333.000.23