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Comparing the latest HemoClear blood washing system to a gold standard centrifugal washing system for the preparation of women's own lost blood for safe reinfusion after vaginal deliveries and caesarean sections

Submission date
11/06/2021

Recruitment status
No longer recruiting

Registration date
20/08/2021

Overall study status
Completed

Last Edited
16/01/2023

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In the developing world many people don't have access to donated blood products. If they lose a lot of blood, for instance after the delivery of a baby, the safe return of their own blood could be lifesaving. However, in order to safely give back lost blood it should first be washed to get rid of the unwanted components, such as bacteria. A device IS used to clean and purify any lost blood so that it is safe to be given back to the mother after delivery should she need it. In comparison with the current cell salvage device the new HemoClear device is a simple filter that is intended to make cell salvage more affordable and available to all around the world. The aim of this study is to use collected blood lost after vaginal and caesarean deliveries and process it with the new HemoClear device and the currently used blood salvage machine. The study is a non-clinical pilot, meaning that the research staff are only running tests on the collected shed blood in the hospital laboratory, and participation will not have any effect on the clinical care participants will receive.

Who can participate?
Pregnant women over the age of 18 years

What does the study involve?
At the time participants are delivering their baby, one of the research team at the hospital will be informed that they are about to have a baby. If they're having a caesarean section, during the operation any lost blood is suctioned into a blood collection reservoir. This is a standard procedure that also occurs outside of the research. Instead of throwing the blood away as normally happens, the research team will add a drug called heparin to the suction container (to stop the blood from clotting) and then after the caesarean was complete, take the suction container for processing and analysis. If participants have an assisted vaginal birth, an under-buttock sterile drape is placed as standard to collect any blood lost for measuring purposes.

Once the baby is born, the blood in the drape is removed and collected in a sterile container for processing and analysis. After tests are performed and the results reported all blood samples will be destroyed. No samples are stored after the completion of the study.

What are the possible benefits and risks of participating?
The blood collected will only be used for investigation in a laboratory to compare the performances of the two devices and will not be given back to participants. There will be no direct health benefits for participants other than to contribute to improved health care for mothers around the world. There also aren't any health disadvantages or risks to participants' health arising from taking part in the study.

Where is the study run from?
Chelsea and Westminster Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2021 to January 2023

Who is funding the study?
European Commission

Who is the main contact?
Dr Philip Barclay
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
294144

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 48128, IRAS 294144

Study information

Scientific Title
Use of the HemoClear system for obstetric cell salvage: A pre-clinical proof of concept to cleanse blood salvaged in caesarean sections and vaginal delivery

Study objectives
The simple, accessible, and cost-effective HemoClear blood salvage filter performs equally well as the gold standard centrifugal salvage device in salvaging red blood cells and washing out harmful non-cellular components.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/02/2021, Health and Social Care Research Ethics Committee A (HSC REC A; Office for Research Ethics Committees Northern Ireland (ORECNI), Customer Care & Performance Directorate, Unit 4, Lissue Industrial Estate West, Rathdown Walk, Moira Road, Lisburn, BT28 2RF, UK; +44 (0)28 9536 1400; prs@hscni.net), REC ref: 21/NI/0015

Study design
Observational clinical laboratory study

Primary study design
Observational

Secondary study design
Clinical laboratory study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Vaginal deliveries and caesarean sections

Interventions
Consenting and collecting participants' samples
Consent will be sought from women scheduled that are about to have a caesarean section or go through assisted vaginal delivery. Collection and measure of blood lost at caesarean section and assisted vaginal births is standard practice. Once delivery is complete, the collected blood in the drape will be transferred by a member of the research team for processing. No clinical or demographic data is collected for any participant.

Processing with cell salvage devices
Prior to processing a small volume of each shed blood volume is taken to determine the blood quality by means of several laboratory analyses. Next the shed blood volume collected from each participant is split into two. The first half is processed with a gold standard cell saver device and the second half is processed with the HemoClear device. The processed blood volumes are taken to the laboratory and analyzed as well. Upon completion of the analysis all blood samples will be discarded.

Statistical analysis
To determine the washing effectivity and comparability of the two washing devices, statistical analysis will be performed with the laboratory results.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
The novel HemoClear device's washing efficiency statistical comparability to the gold standard cell saver, measured using the statistical difference in the amounts of blood cells and non-cellular components after processing with HemoClear compared to processing with the gold standard device

Secondary outcome measures
1. Percentage of maternal blood cells recovered by each device measured by complete blood counts using a haematology analyser, prior to processing of the shed blood and after processing with each device
2. Percentage of neonatal blood cells recovered by each device measured using the Kleihauer-

Betke tests, prior to processing of the shed blood and after processing with each device
3. Percentage of alpha-fetoprotein washed out by each device as a marker of amniotic fluid content measured using a chemistry analyser, prior to processing of the shed blood and after processing with each device
4. Percentage of bacterial load washed out by each device measured using a microbial detection system, prior to processing of the shed blood and after processing with each device
5. Percentage of albumin washed out by each device as a general marker of washing efficiency and removal of proteins, measured using a chemistry analyser, prior to processing of the shed blood and after processing with each device
6. Percentage of lactate dehydrogenase washed out by each device as a market of the amount of dead red blood cells measured using a chemistry analyser, prior to processing of the shed blood and after processing with each device
7. Percentage of heparin washed out by each device as a marker of coagulation, measured using a coagulometer, prior to processing of the shed blood and after processing with each device
8. The effect on the coagulation profile of the blood cells by each device measured by activated partial thromboplastin time and prothrombin time using a coagulometer, prior to processing of the shed blood and after processing with each device

Overall study start date
01/02/2021

Completion date
01/01/2023

Eligibility

Key inclusion criteria
1. Women giving assisted vaginal birth or undergoing caesarean section.
2. Women losing between 500 and 1500 mL of shed blood

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 18; UK Sample Size: 18

Total final enrolment
11

Key exclusion criteria
1. Any patient undergoing caesarean section where cell salvage is clinically indicated and standard practice at West Middlesex University Hospital (i.e. placenta praevia major, the patient is a Jehovah’s Witness etc)
2. Any patients with significant haemoglobinopathy (such as sickle-cell or thalassaemia) where

red cell fragility may
be an issue
3. Any patients taking intrapartum antibiotics
4. Any patient with an active diagnosis of cancer

Date of first enrolment
27/07/2021

Date of final enrolment
01/01/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Chelsea and Westminster Hospital
Chelsea and Westminster Hospital NHS Foundation Trust
369 Fulham Road
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Sponsor information

Organisation
HemoClear B.V.

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Sponsor type
Industry

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. No additional documents available.

Intention to publish date
01/09/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No