ISRCTN13556780 https://doi.org/10.1186/ISRCTN13556780

# A pilot to determine how blood salvage can serve Nigerian patients in need of blood transfusion

**Submission date**
21/03/2024

**Recruitment status**
No longer recruiting

**Registration date**
29/03/2024

**Overall study status**
Completed

**Last Edited**
08/05/2024

**Condition category**
Pregnancy and Childbirth

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

## Plain English summary of protocol

Background and study aims
Having enough blood available for medical procedures like surgeries and childbirth is an important aspect of hospital care. But blood is limited and expensive, so hospitals have to be careful how they use it. Giving someone else's blood to a patient also has risks, like infections or bad reactions.

To solve this problem, hospitals are starting to use a method called Patient Blood Management, which means being careful with how they use blood and trying to avoid giving transfusions if possible. One key part of this is using a process called cell salvage during surgeries. This method collects the patient's own lost blood during an operation, cleans it, and puts it back into the body. This can reduce the need for donor blood, saving money and reducing risks.

In childbirth, losing too much blood can be dangerous, and it's a major cause of maternal deaths worldwide. In Nigeria alone, many pregnant women need a lot of blood each year. Hospitals there often use a lot of blood in the Obstetrics and Gynaecology (OBGYN) department.

To see if using cell salvage could help, the Nigerian National Blood Service Commission will test it in Nigeria's OBGYN department. The test will start by using cell salvage in planned surgeries where blood loss is expected, like cesarean sections. Then, if it works well, they'll use it in emergency cases too. This trial will help the Nigerian National Blood Service Commission to see if using cell salvage could be a good idea for hospitals across the country.

Who can participate?
Women aged between 18 and 65 years old giving birth or undergoing a gynaecological surgical procedure at the University of Abuja Teaching Hospital or the University of Calabar Teaching Hospital may be eligible depending on their need to receive an autologous blood transfusion.

What does the study involve?
At the two pilot centers, an autologous blood transfusion service by microfiltration cell salvage will be implemented followed by a real-world trial of the use of the service. Any woman

admitted to one of the participating hospitals and adhering to the eligibility criteria will be offered the opportunity to use the autologous blood transfusion services. When the woman wishes to make use of the autologous blood transfusion service, her blood lost during the delivery of her baby or surgical procedure is collected. Cleansed with the microfiltration technology and safely given back to her right after processing.

What are the possible benefits and risks of participating?
Participating means that if necessary the doctors will use your own blood during surgery, which can be safer, more efficient, and potentially lead to a quicker recovery. Because it’s the women’s own blood, there's less chance of bad reactions or getting sick from someone else's blood. Moreover, there’s a lower need to rely on others’ donated blood. As well as a reduced risk of catching infections like HIV or hepatitis from donated blood. For participating women receiving their own blood may lead to quicker healing since their body is already familiar with the blood received.

When someone gets blood from a donor, there are risks like getting the wrong blood type or infections. However, using cell salvage, where the patient's blood is collected during surgery, cleaned and returned to them can reduce the need for donor blood. This means fewer risks of reactions or infections. Plus, it can help patients recover faster by reducing the chance of low blood after surgery, which can lead to longer hospital stays and other problems. So, participating in cell salvage shouldn't cause any extra discomfort or risk for patients or researchers.

Where is the study run from?
The University of Abuja Teaching Hospital and the University of Calabar Teaching Hospital

When is the study starting and how long is it expected to run for?
March 2024 to July 2025

Who is funding the study?
Fund for Innovation in Development (FID)

Who is the main contact?
1. National Blood Service Commission: info@nbsc.gov.ng.
2. University of Calabar Teaching Hospital: Prof Etim Ekanem, etimekanem@unical.edu.ng
3. University of Abuja Teaching Hospital: Dr Theresa Otu, ohuneneizeotu@yahoo.co.uk

### Study website
https://fundinnovation.dev/en/projects/an-innovative-technology-for-transfusion-to-mitigate-the-impacts-of-blood-shortage-in-nigeria

# Contact information

### Type(s)
Principal Investigator


### Contact name
Prof Saleh Yuguda

### Contact details
Plot 621, Road 37, 3rd Avenue, Gwarinpa
Abuja

Nigeria
900108
+2347088370905
dg@nbsc.gov.ng

### Type(s)
Scientific

### Contact name
Mrs Agatha Nnabuihe

### Contact details
Plot 621, Road 37, 3rd Avenue, Gwarinpa
Abuja
Nigeria
900108
+2347088370905
agatha.n@nbsc.gov.ng

### Type(s)
Public

### Contact name
Mrs Adetoun Kalejaiye

### Contact details
Plot 621, Road 37, 3rd Avenue, Gwarinpa
Abuja
Nigeria
900108
+2347088370905
Kalejaiye.a@nbsc.gov.ng

## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
UATH HREC PROTOCOL NUMBER: UATH/HREC/PR/365 1.1

## Study information

### Scientific Title

A controlled real-world trial of cell salvage by microfiltration in gynaecologic and obstetric care as pilot to implementation of a national autologous blood transfusion service in Nigeria

## Study objectives
This study is carried out to understand the optimal method of autologous blood transfusion service implementation, including the clinical and practical support requirements for successful implementation in LMIC healthcare setting.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
1. Approved 30/01/2024, UATH Health Research Ethics Committee (University of Abuja Teachning Hospital Gwagwalada P.M.B 228 FCT, Gwagwalada, 228 FCT, Nigeria; +234 98 821 228; uathmrec@yahoo.com), ref: FCT/UATH/HREC/13176

2. Approved 21/03/2024, UCTH Health Research Ethics Committee (Court Rd, Calabar, 540281, Nigeria; None provided; mmeremiku@yahoo.co.uk), ref: UCTH/HREC/33/Vol.III/220

## Study design
Investigator-led multi-centre controlled pilot with stepped-wedged implementation

## Primary study design
Interventional

## Secondary study design
Non randomised study

## Study setting(s)
Hospital, Laboratory, Medical and other records

## Study type(s)
Other, Treatment, Safety, Efficacy

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

## Health condition(s) or problem(s) studied
High-quality cell salvage in obstetric and gyneacologic patients with moderate to high risk of blood loss.

## Interventions
Autologous transfusion of blood cells salvaged by microfiltration technology
Participants in the intervention group will receive an autologous blood transfusion prepared by microfiltration cell salvage technology (HemoClear) during their surgical procedure or delivery. Eligible women who are scheduled to undergo an obstetric or gynaecological procedure will be asked for permission to receive their salvaged blood after it’s been processed by the microfiltration technology. It is standard procedure to collect and measure the amount of blood lost during surgery or childbirth. In parallel to the standard non-sterile collection, a sterile blood

collection system is set up to suction blood for salvage. In case bleeding occurs during their delivery or surgical procedure, and upon the decision of the attending anaesthetist (certified to perform blood salvage), the participating women will receive back their blood cells through a standard autologous blood transfusion procedure as soon as the processed autologous blood unit(s) become(s) available.

### Intervention Type
Procedure/Surgery

### Primary outcome measure
Adoption of the autologous blood transfusion procedure measured using (1) surveys of the health care staff involved in the provision of the autologous blood, (2) autologous blood transfusion exam outcomes as recorded by the health care staff involved in the provision of the autologous blood and (3) participant enrolment rate, directly upon implementation and three months after implementation.

### Secondary outcome measures
1. Volume of autologous blood processed as read from the volume indication on the blood infusion bag upon completion of the autologous blood processing. Upon completion of delivery or surgical procedure, the total volume of autologous blood processed is calculated by adding the volumes of all autologous blood units processed.
2. Volume of autologous blood reinfused as read from the volume indication on the blood infusion bag upon start of the autologous blood reinfusion. Upon completion of delivery or surgical procedure, the total volume of autologous blood reinfused is calculated by adding the volumes of all autologous blood units reinfused.
3. Estimated volume of blood loss as read from the volume indication on the blood collection device before processing of each blood unit. Upon completion of delivery or surgical procedure, the total volume of blood loss is calculated by adding the pre-processed volumes of all autologous blood units lost.
4. Patient blood haemoglobin measured by blood gas analysis before the reinfusion of the first autologous blood unit and after the reinfusion of the last autologous blood.
5. Units of additional donor blood transfused counted after delivery or surgical procedure
6. Processed autologous blood haemoglobin level, red cell count, platelet count and white blood cell count measured by a hematology analyzer complete blood count upon completion of processing of each autologous blood unit

### Overall study start date
01/03/2024

### Completion date
01/07/2025

## Eligibility

### Key inclusion criteria
1. Undergoing obstetric or gynaecologic procedures
2. Ability to provide informed consent, direct or by a relative representative
3. Procedure with estimated blood loss of at least 500mL

### Participant type(s)
Patient

**Age group**
Adult

**Lower age limit**
18 Years

**Upper age limit**
65 Years

**Sex**
Female

**Target number of participants**
300

**Key exclusion criteria**
1. Sickle cell disease
2. Active malignancy contraindicated to cell salvage e.g. abdominal cancer
3. Excessive contamination of the wound field with bacterial contamination

**Date of first enrolment**
01/05/2024

**Date of final enrolment**
01/01/2025

# Locations

**Countries of recruitment**
Nigeria

**Study participating centre**
**University of Calabar Teaching Hospital**
Teaching Hospital Main Site, Calabar South
Calabar
Nigeria
540281

**Study participating centre**
**University of Abuja Teaching Hospital**
Gwagwalada-Zuba, Gwagwalada, Federal Capital Territory
Abuja
Nigeria
902101

# Sponsor information

**Organisation**
National Blood Service Commission

**Sponsor details**
Plot 621, Road 37, 3rd Avenue, Gwarinpa
Abuja
Nigeria
900108
+234 7088370905
info@nbsc.gov.ng

**Sponsor type**
Government

**Website**
https://nbsc.gov.ng/

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
Fund for Innovation in Development

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**
01/07/2025

**Individual participant data (IPD) sharing plan**
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

**IPD sharing plan summary**
Published as a supplement to the results publication