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Cell SALVage in Obstetrics

Submission date
18/06/2012

Recruitment status
No longer recruiting

Registration date
25/06/2012

Overall study status
Completed

Last Edited
24/02/2020

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Donated blood is a precious resource. Having blood available is essential for major procedures including joint replacement, cardiac surgery, organ transplantation, cancer care and the management of major trauma. When there is no blood available, this reduces the ability of the NHS to deliver high quality health care wherever it is needed, and all at the same time. There may be postponements or cancellation of operations if blood is required elsewhere. Intraoperative cell salvage (IOCS) collects the patients own blood lost during an operation, cleans it and returns it to their circulation. It reduces the amount of donor blood given in certain operations. Its use in Caesarean section (CS) has not yet been adequately examined. The National Institute of Clinical Excellence (NICE) recommends IOCS for massive blood loss in an emergency, but has called for evidence from clinical trials to support its routine use. This study will assess if IOCS during Caesarean section reduces the need to give a donor blood transfusion.

Who can participate?
Around 3050 women at risk of bleeding will be studied. As many women as possible booked at around 17 large obstetric units will be given information about the study, prior to birth. Those who deliver by Caesarean section and are eligible for the study will be asked if they would like to participate.

What does the study involve?
Half of the participants will be randomly allocated to IOCS during surgery, and half will receive usual care with donor blood transfusion if necessary. The necessity for transfusion will be recorded for each group. Other maternal health and cost outcomes will be collected. Participation in the study will be from the time of admission to hospital to the time of discharge. There will be no additional tests required but participants will be asked to complete a short questionnaire prior to discharge. The research team is hand-picked from regional centres across England, Scotland and Wales and includes national experts in obstetrics, anaesthesia, cell salvage, health technology assessment and health economics.

What are the possible benefits and risks of participating?
The benefits are uncertain (hence the need for the trial). There is a possibility that IOCS may reduce the need for donor blood transfusion, and the risks associated with this. Blood given during Caesarean section is from blood donations. All blood used in the UK is thoroughly screened for infections and is completely safe, as long as you are given the correct blood group.

Very rarely, mistakes are made and the wrong blood group is given or the recipient has a reaction to the blood. IOCS may, by improving iron levels, allow women to leave hospital sooner and reduce the chance of side effects. There are two concerns about using the cell saver machine during Caesarean sections. Neither concern is related to the health of your baby. Historically, the cell saver was not used in Caesarean sections because it was thought that it might increase the chance of a woman developing a serious condition called 'Amniotic Fluid Embolism'. This is where some of the fluid surrounding the baby in the womb enters the mother's blood stream with serious consequences. More recent work shows that it is highly unlikely that IOCS could cause this condition, but we can never be 100% certain. The second concern is of Rhesus disease in any future babies. This can happen when a woman with the blood type known as 'rhesus-negative' (Rh-) has a baby with the blood type rhesus-positive (Rh+). If the mother's blood comes into contact with the baby's blood, the mother's immune system then produces antibodies that are capable of attacking her baby's blood cells and these antibodies are activated in all future pregnancies when the baby is Rh+. It is possible that the mother's blood can come into contact with the baby's blood during a normal delivery but it is also possible during the IOCS procedure. The exposure to baby's blood is measured using a test called the Kleihauer test. All rhesus-negative women who have a Caesarean section have an injection soon after delivery to prevent these antibodies developing; this is called an anti-D antibody injection. So, participation in the study or having IOCS will not be any different from standard practice in preventing Rhesus disease.

Where is the study run from?
At least 17 large UK obstetric units in collaboration with the UKCRN registered Pragmatic Clinical Trials Unit (PCTU) at Bart's and the London School of Medicine.

When is study starting and how long is it expected to run for?
June 2013 to April 2016

Who is funding the study?
National Institute of Health Research, Health Technology Assessment Programme (NIHR HTA) (UK)

Who is the main contact?
Professor Khalid Khan
k.s.khan@qmul.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Khalid Khan

Contact details
Professor of Women's Health and Clinical Epidemiology
Women's Health Research Unit, Blizard Institute
Bart's and The London School of Medicine
Queen Mary, University of London
58 Turner Street
London

United Kingdom
E1 2AB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 10/57/32, Version 6, 12/09/2014

Study information

Scientific Title
A randomised controlled trial of intra-operative cell salvage during caesarean section in women at risk of haemorrhage

Acronym
SALVO

Study objectives
Primary Objective:
To determine if the routine use of intra-operative cell salvage (IOCS) during caesarean section (CS), in women at risk of haemorrhage, reduces the need for donor blood transfusion in comparison to current practice.

Secondary Objectives:
1. To determine the effect of IOCS on secondary outcomes including the number of units of donor blood transfused, mean fall in serum haemoglobin level and maternal morbidity resulting from post-operative anaemia (time to first mobilisation, duration of hospital stay, and immediate multidimensional fatigue inventory.
2. To determine if the routine use of IOCS during CS, in women at risk of haemorrhage, is cost effective in comparison to current practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North-West Haydock, ref: 12/NW/0513

Study design
Individually randomised controlled multi-centre study with cost-effectiveness analysis

Primary study design
Interventional

Secondary study design

Randomised controlled trial

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
Haemorrhage / Caesarean Section (CS)

Interventions
Intra-operative Cell Salvage (IOCS): A technique which allows the blood lost during surgery to be returned to the patient. Blood is aspirated from the surgical field; the red cell component isolated by centrifugation and after washing and filtration, re-transfused. The ability to return salvaged blood is dependent on sufficient volume being collected and processed. Blood will be uniformly returned to women in the cell salvage group if this volume threshold is reached.

The control group will receive current practice (without cell salvage) which may involve donor blood transfusion.

It is not possible to conduct a blinded study, since group allocation will be self-evident. In life threatening acute haemorrhage, women will be managed at the discretion of attending clinicians, in line with Centre for Maternal and Child Enquiries (CMACE) guidance, potentially including the use of cell salvage in the control arm. The indications for postoperative donor blood transfusion will be set according to local protocols in each hospital and deviations from this criterion will be monitored.

Intervention Type
Procedure/Surgery

Primary outcome measure
The proportion of women needing peripartum transfusion. For the IOCS group this is measured by the use of donor blood transfusion; transfusion of routinely salvaged blood as part of the intervention will not count as an event. For the standard care group this is measured by the use of donor blood transfusion and/or the use of salvaged blood transfusion set up as an emergency to deal with haemorrhage.

Secondary outcome measures
1. Severity of events quantified as the volume of blood transfused, where transfusion is defined as above for the primary outcome - i.e. donor blood transfusion in the IOCS group, and donor blood transfusion plus salvaged blood transfusion set up as an emergency in the standard care group
2. Time to first mobilisation after CS
3. Length of hospital stay
4. Multidimensional Fatigue Inventory (MFI)
5. Resources used intra- and post-operatively, including IOCS consumables and donor blood

transfusions
6. Costs of staff training, service procurement and provision of care will be collected alongside clinical outcomes
7. Safety Outcomes:
7.1. Pre- and post-operative serum haemoglobin, and mean fall in haemoglobin level
7.2. Maternal exposure to fetal blood measured by Kleihauer test
7.3. Requirement for and the dose of anti-D antibody administered
8. Process outcomes
8.1. The number of cases in the IOCS arm where sufficient blood is harvested for re-transfusion
8.2. Volume of blood returned in IOCS (mean/SD)
8.3. Proportion of transfusion reaction associated with allogeneic donor blood transfusion
8.4. Episodes of technical failure of IOCS

Overall study start date
01/10/2012

Completion date
31/10/2016

Eligibility

Key inclusion criteria
1. 16 years of age or older
2. Delivery by elective or emergency caesarean section with an identifiable increased risk of haemorrhage
3. Ability to provide informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
3050

Key exclusion criteria
1. Elective first Caesarean section for maternal request or breech presentation
2. Sickle cell disease
3. Active malignancy contraindicated to CS e.g. abdominal cancer
4. Cultural or social beliefs contraindicating blood transfusion e.g. Jehovah's Witnesses
5. Significant antibodies making it difficult to find cross matched blood for transfusion
6. Unable to understand written and spoken English

Date of first enrolment
01/06/2013

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Mary, University of London
London
United Kingdom
E1 2AB

Sponsor information

Organisation
Queen Mary, University of London (UK)

Sponsor details
c/o Gerry Leonard
Head of Resources
Joint R&D Office
5 Walden Street
London
England
United Kingdom
E1 2EF
+44 (0)20 7882 7260
sponsorsrep@bartshealth.nhs.uk

Sponsor type
University/education

Website
http://www.bartsandthelondon.nhs.uk/our-services/research-and-development/contact-us/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/10/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/12/2017		Yes	No
Results article	results	01/01/2018		Yes	No
Results article	results	19/02/2019		Yes	No