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Post-Partum Haemorrhage Butterfly study (II): clinical testing and commercialisation

Submission date
14/08/2017

Recruitment status
No longer recruiting

Registration date
11/09/2017

Overall study status
Completed

Last Edited
13/03/2023

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
Postpartum hemorrhage (PPH) described when there is serious bleed right after giving birth. Some bleeding is normal after birth, but when there is a lot of blood, women need medication, blood transfusions or other serious surgical methods. The PPH (Postpartum Haemorrhage) Butterfly is a simple, low cost device which has been developed at the University of Liverpool for management of heavy bleeding immediately after childbirth (PPH). The research question is relevant to women in that if the device is successful in "turning off the tap" there will be direct tangible benefits to the women and may avoid the need for women to undergo surgical procedures in theatre for treatment.

Who can participate?
Women aged 16 and older with PPH following vaginal birth which is unresponsive to the first line management.

What does the study involve?
Participants who have PPH receive the standard treatment in line with the clinic but also have the PPH Butterfly used in an attempt to stop the bleeding. The device is used for a maximum of five times for five minutes to compress the uterus. Participants are followed up for one hour post PPH and until she leaves the hospital. Women who received the PPH Butterfly have their outcomes compared to the records of women who did not receive the PPH Butterfly to see how beneficial it is.

What are the possible benefits and risks of participating?
Participants may benefit from the device working to stop the bleeding in a short time period, saving the trauma of having an extended bleed and possible surgery. This may also have psychosocial benefits as post-partum surgery would mean that the woman is separated from her baby for a period of time which may affect bonding with her baby and establishing breast feedings. The risks to the women are minimized by receiving PPI standard treatment alongside the use of the PPH Butterfly. The device has been tested and a comprehensive education programme has been developed.

Where is the study run from?
Liverpool Women's Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2016 to March 2019

Who is funding the study?
University of Liverpool (UK)

Who is the main contact?
1. Mrs Mira Ebringer
m.ebringer@liverpool.ac.uk
2. Professor Andrew Weeks
aweeks@liverpool.ac.uk

Study website
https://www.liverpool.ac.uk/translational-medicine/research/pph-butterfly/

Contact information

Type(s)
Public

Contact name
Mrs Mira Ebringer

Contact details
Sanyu Research Unit
Dept of Women's and Children's Health
University of Liverpool
1st Floor
Liverpool Women's Hospital
Liverpool
United Kingdom
L8 7SS
+44 (0)151 795 7872
m.ebringer@liverpool.ac.uk

Type(s)
Scientific

Contact name
Prof Andrew Weeks

Contact details
Sanyu Research Unit
Dept of Women's and Children's Health
University of Liverpool
Liverpool Women's Hospital
Crown Street
Liverpool

United Kingdom
L8 7SS
+44 (0)151 795 9578
aweeks@liverpool.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
31655

Study information

Scientific Title
An open label, phase II, un-randomised trial of a novel medical device to manage post-partum haemorrhage, with historical controls

Study objectives
The aim of this study is to assess the difference in clinical outcomes of women who experience PPH and who were treated under the Liverpool Women's Hospital standard clinical treatment pathway for PPH (controls) with those who are treated with the PPH Butterfly.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NW Liverpool Central REC, 05/07/2017, ref: 17/NW/0373

Study design
Non-randomised; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Secondary study design
Non randomised 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
Specialty: Reproductive health and childbirth, Primary sub-specialty: General Gynaecology; UKCRC code/ Disease: Reproductive Health and Childbirth/ Complications of labour and delivery

Interventions
The intervention to be used is an innovative medical device, the PPH Butterfly, which has been designed by an NHS Consultant Obstetrician. In this trial the women are treated for PPH in line with the Liverpool Women's Hospital clinical care pathway on PPH but the PPH Butterfly is used in an attempt to "turn off the tap" and bring a halt to bleeding. The device will be used for up to a maximum of 5 iterations of 5 minutes of employing the device to achieve uterine compression. Follow-up on the woman will be for one hour post PPH and then until she leaves the Liverpool Women's Hospital. The device has both treatment and diagnostic properties in determining where the source of the bleeding emanates from i.e. uterine or vaginal bleeding caused by intra-partum lacerations.

236 historical controls (2:1) are be used to assess the difference in clinical outcomes of women who experienced a PPH and who were treated under the Liverpool Women's Hospital standard clinical treatment pathway for PPH (controls) with those women who were treated with the PPH Butterfly.

Intervention Type
Device

Primary outcome measure
Additional blood loss of over 1000ml after first use of the device at 24 hours after birth

Secondary outcome measures
1. Mean estimated blood loss (from time of insertion of the device until cessation of active bleeding). Overall estimates will be based on visual estimates supplemented with information from weighing of swabs and collected blood where available.
2. Use of additional interventions within 24 hours to control ongoing bleeding, and whether this was a haemostatic drug (e.g. ergometrine, carboprost, tranexamic acid), or surgical intervention (including Bakri balloon and examination under anaesthetic).
3. Any organ dysfunction as defined by the WHO Maternal ‘near-miss’ Approach (Say 2009). The WHO maternal near-miss tool is a composite measure consisting of 25 clinical, laboratory and management-based criteria (WHO 2011). Specifically relevant to haemorrhage are shock, blood transfusion, coagulopathy and hysterectomy, all of which will be reported separately as well as in this composite outcome of organ dysfunction as recommended by the COS.
4. Number of women receiving a blood transfusion (defined as ‘any blood transfusion or cell salvage of over 300mls within 48 hours of birth’) and the number of units of blood received.
5. Shock (defined as any systolic blood pressure under 100mmHg within 24 hrs of recruitment

The core outcome set available via http://www.comet-initiative.org/studies/details/706 has been consulted in the construction of the study outcome measures.

Overall study start date
01/04/2016

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Women with PPH following vaginal birth which is unresponsive to first line management (usually intravenous or intramuscular oxytocin +/- ergometrine)
2. Aged over 16

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 118; UK Sample Size: 118

Total final enrolment
57

Key exclusion criteria
1. Women assessed antenatally to have learning difficulties that may have the potential to impair their decision making
2. Women aged < 16 years of age
3. Women who cannot read or understand the level of English used in the study documentation
4. Women whose baby is stillborn
5. Women whose PPH occurs more than 24 hours following birth
6. Women who have undergone Female Genital Mutilation/vaginal surgery which is unreversed (assessed antenatally)
7. Women with clotting disorders; either longstanding or following intrapartum events
8. Women in whom the third stage of labour is not complete (placenta remains in situ) or who had a retained placenta of over 30 minutes
9. Women who have had a caesarean section
10. Women who have fainted or who are unconscious (including those under anaesthetic) during the PPH
11. Women whose PPH is clinically diagnosed after 1 hour of baby's birth

Date of first enrolment
01/11/2017

Date of final enrolment
21/12/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Liverpool Women's Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS

Sponsor information

Organisation
University of Liverpool

Sponsor details
2nd Floor
Waterhouse Building
Brownlow Street
Liverpool
England
United Kingdom
L69 3QL
+44 151 794 8739
sponsor@liverpool.ac.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Central Commissioning Facility (CCF); Grant Code: II-LA-0715-20008

Results and Publications

Publication and dissemination plan
It is planned for the results to be written up for publication along with the design process. All papers will be written with a view to submitting into high level health journals. A lay summary will also be prepared for the women who participated in the study – participants will be asked whether they wish to receive it at the time of recruitment.

Intention to publish date
30/04/2023

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Economic evaluation	21/01/2023	03/02/2023	Yes	No
Other publications		04/03/2023	13/03/2023	Yes	No
HRA research summary			28/06/2023	No	No