

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

Submission date 14/08/2017	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 11/09/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 13/03/2023	Condition category Pregnancy and Childbirth	☐ 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?
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Contact information

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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 to 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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

Liverpool Women's Hospital

Crown Street

Liverpool

United Kingdom

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Sponsor information

Organisation

University of Liverpool

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

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		21/01/2023	03/02/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Economic evaluation	04/03/2023	13/03/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes