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Evaluation of intrauterine balloon tamponade efficacy with condom catheter in the severe postpartum hemorrhage management in Benin and Mali

Submission date
05/05/2013

Recruitment status
No longer recruiting

Registration date
09/09/2013

Overall study status
Completed

Last Edited
27/02/2017

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
The decrease of maternal death is one of the millennium goals defined by the World Health Organisation (WHO). Bleeding after delivery (postpartum hemorrhage) is the first cause of maternal death in countries with low incomes, and in particular in sub-Saharan African countries. Intrauterine tamponade with a condom catheter is a possible treatment for postpartum hemorrhage in these countries. The aim of this study is to demonstrate that the intrauterine tamponade by condom catheter reduces death and severe disease rates in cases of severe postpartum hemorrhage.

Who can participate?
All women giving birth in one of the centers participating in the study and presenting a severe postpartum hemorrhage, not responding to the first-line of treatment (oxytocine + uterine massage + uterine revision). Women under the legal age will be able to participate in this study after authorization of a legal representative.

What does the study involve?
Patients are randomly allocated to one of two groups. One group receives intrauterine balloon tamponade by condom catheter and usual treatment (misoprostol) and the other receives usual treatment (misoprostol alone).

What are the possible benefits and risks of participating?
The intrauterine balloon tamponade seems to be a promising technique in the treatment of the postpartum hemorrhage. In order to avoid any loss of luck for the patients participating in the study, the intrauterine balloon tamponade will be given to patients belonging to the group receiving usual treatment. There are no risks linked to the treatment by misoprostol, except the minor side effects of this product: nausea, vomiting, shiver, fever and abdominal pain (all of these are specified in the information note for the patients). The potential risk identified for the intrauterine balloon tamponade is a risk of infection. However, among 239 cases of intrauterine

balloon tamponade tested in low-income countries, no case of infection was indicated. Furthermore, this study plans a preventive treatment by antibiotics to prevent this risk of infection.

Where is the study run from?
There are seven centers taking part in this study:
Four in Cotonou:
1. Reference health center: Hôpital Mère-Enfant de la Lagune (HOMEL)
2. District hospital: Abomey-Calavi hospital
3. District hospital: Menontin hospital
4. Peripheral maternity of Missessin
Three in Bamako, Mali:
1. Reference health center of Commune V
2. Community health center of Sabalibougou I
3. Community health center of Torokorobougou

When is the study starting and how long is it expected to run for?
May 2013 to December 2015

Who is funding the study?
1. Institut de Recherche pour le Développement (IRD) (France)
2. Muskoka Fund for operational research, UNICEF, Regional Office for Central and Western Africa

Who is the main contact?
1. Mrs Cecile Bodin (cecile.bodin@gmail.com)
2. Dr Alexandre Dumont (alexandre.dumont@ird.fr)

Contact information

Type(s)
Scientific

Contact name
Dr Alexandre Dumont

ORCID ID
https://orcid.org/0000-0003-3826-0193

Contact details
IRD UMR 216
Faculté de pharmacie
4 avenue de l'observatoire
Paris
France
75006
-
alexandre.dumont@ird.fr

Additional identifiers

Protocol serial number
TIUHPPI v15/04/2013

Study information

Scientific Title
Evaluation of intrauterine balloon tamponade efficacy with condom catheter and misoprostol (usual treatment) compared to misoprostol alone in the severe postpartum management hemorrhage management in Benin and Mali: a randomized controlled trial

Acronym
Condom PPH

Study objectives
The aim of this study is to demonstrate that the intrauterine tamponade by condom catheter reduces mortality and severe morbidity rate in case of severe postpartum hemorrhage.

The hypothesis is that the mortality and severe morbidity rate (recourse to an invasive surgery) should reach 25% in the control group and 6% in the intervention group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. France: Professional ethics and Ethics Consultative Committee of the Research Institute for Development (CCDE IRD), 29/01/2013
2. Mali: Ethics Committee of the Faculty of Medicine, Pharmacy and Odonto-Stomatology (FMPOS), 19/04/2013, ref: 2013/35/CE/FMPOS
3. Benin: Ethics and Research Committee of the Institute of the Biomedical Applied Sciences (ISBA) of Benin, 16/11/2012

Primary study design
Interventional

Study design
International randomized controlled trial multicenter open-label in two parallel groups

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gynecology-obstetrical/severe postpartum hemorrhage

Interventions
The first line of post-partum hemorrhage (PPH) management is an injection of oxytocin + the realisation of an uterine massage and a uterine revision. These 3 treatments have to be realised jointly. Thus, if neither the injection of oxytocin, nor the uterine massage and the uterine revision allows to stop the PPH, the second line of PPH management has to be realized (administration of misoprostol or misoprostol + condom catheter tamponade.

Women presenting a postpartum hemorrhage resistant to oxytocin and first line laborers (uterine massage + uterine revision), will be randomized in order to receive:
1. The usual treatment to the posology of 5 tablets of Misoprostol 200 µg (intra-rectal) or 3 tablets of Misoprostol 200 µg (sub-lingual) immediately associated with an intrauterine balloon tamponade by condom-catheter
2. Only the usual treatment to the posology of 5 tablets of Misoprostol 200 µg (intra-rectal) or 3 tablets of Misoprostol 200 µg (sub-lingual)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Misoprostol

Primary outcome(s)
The primary outcome is a composite outcome: individual recourse to an invasive surgery (arterial ligatures, uterine compressive sutures, hysterectomy of haemostasis) and/or maternal death before the hospital release

Key secondary outcome(s)
Each element of the composite primary outcome is related to the point 1 and 2 only. So the secondary outcomes are formed by the 2 elements of the primary outcome measured separately and we will also measure three other outcomes: bleedings>1000 mL, necessity of a transfusion, necessity of a transfer.
1. Invasive intervention rate (arterial ligatures, uterine compressive sutures or hysterectomy of haemostasis): number of women having received an invasive intervention divided by the number of women included
2. Hospital maternal mortality rate (number of women included in the study and died before the hospital release divided by the number of inclusive women)
3. Bleeding > 1000 mL.
4. Necessity of a transfusion
5. Necessity of a transfer

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Having given birth by vaginal way, in one of the selected establishments
2. After 28 weeks of amenorrhea, or foetus > 1000 g
3. Presenting a HPPI resisting the oxytocine and the first-line laborers (uterine massage + uterine revision)
4. Having given its oral consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Having given birth by caesarian
2. Presenting a contraindication or an allergy known about prostaglandins
3. Presenting an allergy to latex
4. Presenting a clinical Chorioamnionitis
5. Presenting a secondary postpartum hemorrhage, cervico-vaginal tears without uterine bleeding, an uterine break, or a placenta accreta

Date of first enrolment
14/10/2013

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Benin

Mali

Study participating centre
Reference health center: Hôpital Mère-Enfant de la Lagune (HOMEL)
Cotonou
Benin
-

Study participating centre
District hospital: Abomey-Calavi Hospital
Cotonou
Benin
-

Study participating centre
District hospital: Menontin Hospital
Cotonou

Benin
-

Study participating centre
Peripheral maternity of Missessin
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Benin
-

Study participating centre
Reference health center of Commune V
Bamako
Mali
-

Study participating centre
Community health center of Sabalibougou I
Bamako
Mali
-

Study participating centre
Community health center of Torokorobougou
Bamako
Mali
-

Sponsor information

Organisation
Institute of Research for Development (Institut de Recherche pour le Développement) (IRD)

ROR
https://ror.org/05q3vnk25

Funder(s)

Funder type
Research organisation

Funder Name
Institute of Research for Development (Institut de Recherche pour le Développement) (IRD), Paris (France) (ref: TIUHPPI)

Funder Name
Muskoka Fund for operational research, UNICEF, Regional Office for Central and Western Africa

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Alexandre Dumont (alexandre.dumont@ird.fr)

IPD sharing plan summary
Available on request