ISRCTN01202389 https://doi.org/10.1186/ISRCTN01202389

# 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
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

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

### 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
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 measure
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

## Secondary outcome measures
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

### Overall study start date
01/05/2013

### 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

### Age group
Adult

### Sex
Female

### Target number of participants
The target number of patients to be included in this trial is 110 women (55 in each group) with a risk α=0.05 and a power of 80 % with a bilateral formulation.

### 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**
Cotonou
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)

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**Sponsor type**
Research organisation

**Website**
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**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

### Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal around March 2017

### Intention to publish date
01/03/2017

### 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