ISRCTN70408620 https://doi.org/10.1186/ISRCTN70408620

A study of self-administered Misoprostol to prevent bleeding after childbirth in the community (MamaMiso)

Submission date
17/11/2011

Recruitment status
No longer recruiting

Registration date
28/12/2011

Overall study status
Completed

Last Edited
19/06/2018

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
Heavy bleeding after childbirth, known as postpartum haemorrhage (PPH), is a major cause of maternal death in the developing world. PPH can be prevented using uterotonic drugs, which cause the uterus (womb) to contract. Misoprostol can be used to prevent PPH as it is affordable, has a long shelf-life, and can be taken by mouth (orally). Currently misoprostol is mostly used in healthcare facilities and self-administration at home is not promoted. The aim of this study is to assess the effectiveness and safety of misoprostol tablets taken immediately after home delivery for the prevention of PPH.

Who can participate?
Pregnant women (more than 34 weeks gestation) living in the participating villages of Mbale district of Eastern Uganda.

What does the study involve?
Participants are randomly allocated to be given either a trial pack of misoprostol or placebo (dummy) tablets to be self-administered orally after delivery. Participants are trained on how to take the pills following delivery and a picture guide will also be included with the pills.

What are the possible benefits and risks of participating?
Not provided at time of registration.

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?
January 2012 to January 2015.

Who is funding the study?
Bill and Melinda Gates Foundation (USA).

Who is the main contact?
Prof. Andrew Weeks
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v5.6 10/07/2011

Study information

Scientific Title
A pilot study of self-administered Misoprostol to prevent bleeding after childbirth in the community (MamaMiso)

Study objectives
Postpartum hemorrhage (PPH) is a major cause of maternal death in the developing world. An important strategy in the prevention of deaths is the use of uterotonic drugs for PPH prophylaxis. Misoprostol has been recognized as an option for preventing PPH as it is economical, heat stable, has a long shelf-life, and can be taken orally.

We envisage that the use of self-administered misoprostol after home births among mothers would be associated with a peri-partum fall in hemoglobin value of over 20% (the outcome of a fall of 2g/dl will also be tested in the pilot).

The objective of the main study will be to assess the effectiveness and safety of antenatal administration of misoprostol tablets (600mcg) for self administration immediately following home delivery for the prevention of postpartum haemorrhage. The objectives of the pilot study are to test the integrity of the study protocol, to test the randomization procedure, to assess the acceptability of the intervention, to test the logistics of follow-up, to test the data collection forms, to validate the quality of life questionnaire in this population and to determine the recruitment rate to help study planning.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Mbale Regional Hospital Institutional Research Committee (MRHIRC), 25/03/2011, ref: REIRC 010/2011
2. University of Liverpool (UK), 05/08/2011, ref: UoL000694
3. Uganda National Council for Science and Technology (UNCST), 07/10/2011, ref: HS 1059

Study design
Placebo-controlled randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the main contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Postpartum hemorrhage (PPH)

Interventions
Once the pregnant women are seen in antenatal clinic and give informed consent to participate in the trial, they will be given either trial pack of misoprostol (600mcg) or identical placebo to be self-administered orally after delivery. She will be trained to take the pills following delivery using adapted teaching tools used successfully in Nepal and Afghanistan. A picture guide on how to take the medication will also be included with the mediation in the study neck purse.

Intervention Type
Drug

Phase

Not Applicable

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

Primary outcome measure
Peri-partum fall in hemoglobin value of over 20% (the outcome of a fall of 2g/dl will also be tested in the pilot) following use of self-administered misoprostol after home birth

Secondary outcome measures
1. The rate of poor maternal and fetal health at 3-5 days after delivery
2. Side effects, and safety (to include transfer to hospital, surgical intervention, blood transfusion and maternal death)

The exact outcomes as well as the power calculations will only be finalized once the pilot study is completed.

Overall study start date
01/01/2012

Completion date
01/01/2015

Eligibility

Key inclusion criteria
1. Pregnant women living in the recruitment villages of Mbale district at more than 34 weeks gestation
2. High risk women will not be excluded from the pilot study, even if they state their intention to deliver in a health facility

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
The pilot will allow us determine the primary outcome and thereafter help us determine the number for the main study. The pilot will recruit as many as possible during this time.

Key exclusion criteria
1. Any pregnant woman with a known allergy to misoprostol or other prostaglandins
2. Any woman under 18 years old (unless she is an emancipated minor)

Date of first enrolment
01/01/2012

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
England

Uganda

United Kingdom

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

Sponsor information

Organisation
University of Liverpool (UK)

Sponsor details
Department of Women's and Children's Health
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Sponsor type
University/education

Website
http://www.liv.ac.uk

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	14/09/2015		Yes	No
Results article	results	26/10/2017		Yes	No