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Effect of gentamicin in combination with metronidazole to prevent of post caesarean infection

Submission date
05/09/2011

Recruitment status
No longer recruiting

Registration date
12/09/2011

Overall study status
Completed

Last Edited
10/02/2016

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A caesarean section is an operation in which an incision (cut) is made through the abdomen and uterus of a pregnant woman to deliver a baby. It is a common operation worldwide. The risk of infection after this operation is five times higher compared to vaginal birth (normal birth). Anti-bacterial drugs are usually given to the woman about to undergo caesarean section 30-60 minutes before the operation to reduce the risk of infection after the operation. Provision of a single dose of these drugs is recommended by many centers because repeated or multiple doses not have any added advantage. Infection after caesarean section is among the top five causes of admission at Bugando medical centre post delivery wards. We do not have a regulated course of antibacterial drugs which has resulted from our own studies. As a result, most of the time, pregnant women who are planned for caesarean section receive repeated doses of antibacterial drugs. The aim of this study is to assess the effectiveness of a single dose of gentamicin in combination with metronidazole compared to multiple doses of the same drugs in the prevention of infection after caesarean section.

Who can participate?
All pregnant women who present in the delivery room with labor pain and later planned for caesarean section.

What does the study involve?
Participants are randomly allocated into two groups. Participants in one group receive a single dose of gentamicin in combination with metronidazole 30-60 minutes before their operation and participants in the second group receive the same drugs before the operation and continue with metronidazole eight hourly for 24 hours.

What are the possible benefits and risks of participating?
There are no risks in participating in this study because we are not using a new treatment. The treatments we are planning to use are the ones commonly used at this department.

Where is the study run from?
Bugando medical centre, Mwanza (Tanzania)

When is the study starting and how long is it expected to run for?
October 2011 to June 2012

Who is funding the study?
Weill Bugando University College of Health Sciences (Tanzania)

Who is the main contact?
Dr Fadhili Lyimo
fadhili1810@yahoo.com

Contact information

Type(s)
Scientific

Contact name
Dr Anthony Massinde

Contact details
Bugando University College of Health Sciences
Box 1464
Mwanza
Tanzania
-
+255 (0)754 465 957
amassinde@bugando.ac.tz

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Efficacy of single dose of gentamicin in combination with metronidazole versus multiple doses for prevention of post caesarean infection: a randomised controlled trial

Study objectives
There is a significant difference in cumulative incidence of post caesarian infection between clients under single dose antibiotic regime and women under multiple doses antibiotic regimen.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Bugando University College of Health Sciences Research Committee, 22/08/2011, ref: BREC/001/39/2011

Study design
Interventional open-label two-armed randomised single-centre study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-caesarean infection

Interventions
Study participants will be randomly allocated in two study arms, A and B.

Study Arm A:
Will receive a single intravenous single dose gentamicin (160mg) plus metronidazole 500mg 30-60 minutes before operation

Study Arm B:
Will be those who will receive multiple doses; gentamicin (160mg) plus metronidazole (500mg) 30-60 minutes after operation for 24 hours

Simple randomization will be used, 200 similar envelopes will be prepared and inside each of the 100 sealed envelopes there will be small paper marked study arm A. The remaining sealed envelopes will contain small papers marked study arm B. All sealed envelopes will be mixed thoroughly in a box before selection of an envelope is done. Each study participant will select one sealed envelope and give it to the researcher to open. Then will get antibiotic prophylaxis according to her allocated group.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gentamicin, metronidazole

Primary outcome(s)
1. Surgical site infection will be our primary outcome - the assessment for any evidence of surgical site infection will be done 72 hours after caesarian section as well as on follow up days (day 7 and day 30 post caesarean section)
2. Presence of fever (febrile morbidity), signs and symptoms of abdominal wound infection or endometritis will indicate surgical site infection
3. Febrile morbidity will be defined by temperature above 380 C at least 4 hours apart on two or more occasions excluding the first 24 hours after delivery

4. Abdominal wound infection will be defined by partial or total dehiscence or presence of purulent or serous discharge from the wound with indurations, warmth and tenderness
5. Endometritis will be defined by presence of fever (380 C or above) in association with one or more of the following: uterine tenderness or foul smelling lochia
6. In both groups, the bladder catheter will be removed after 24 hours. Wound care will follow the standard scheme in both groups, the occlusive dressing applied in the theatre and removed after 48 hours.
7. Patient will be discharged on day 3 if there was no sign of infection or complication and asked to return on day 7 in order to remove stitches. Then she will come on the day 30 post caesarean section for reassessment. On day 7 and day 30, axillary temperature will be measured, and abdomen and wound will be examined for signs of infection and sutures will be removed on first follow up visit.

Key secondary outcome(s))
No secondary outcome measures

Completion date
30/06/2012

Eligibility

Key inclusion criteria
All pregnant women planned for emergency caesarean section and have consented for the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Fever (temperature of 38 degrees and above)
2. Prolonged obstructed labor
3. Prolonged premature rupture of membranes (rupture of membrane more than twelve hours)
4. Features of chorioamnionitis (i.e. foul smelling lochia, uterine tenderness associated with fever)
5. Allergic to the antibiotics used in the study
6. Used antibiotics in the 24 hours preceding the operation
7. Will receive blood transfusion before, during or after caesarian section
8. Non pregnant women

Date of first enrolment
01/10/2011

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
Tanzania

Study participating centre
Bugando University College of Health Sciences
Mwanza
Tanzania
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Sponsor information

Organisation
Bugando University College of Health Sciences (Tanzania)

ROR
https://ror.org/015qmyq14

Funder(s)

Funder type
University/education

Funder Name
Bugando University College of Health Sciences (Tanzania)

Results and Publications

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?

Protocol article	protocol	21/06/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes