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Prevention of post-caesarean infections in low resource countries: is a single dose as adequate as a multiple dose antibiotic regiment? A randomised controlled trial

Submission date
21/01/2008

Recruitment status
No longer recruiting

Registration date
05/02/2008

Overall study status
Completed

Last Edited
05/02/2008

Condition category
Infections and Infestations

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Is the administration of a single prophylactic dose of ampicillin and metronidazole before caesarean section as effective as a multiple day regimen of these antibiotics to prevent postpartum maternal infection in a low resource setting? A randomised controlled trial

Study objectives

Single dose antibiotic prophylaxes is as effective as a multiple dose scheme in women undergoing a caesarean section in low resource setting in preventing postoperative infections.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the National Institute for Medical Research, Dar es Salaam (Tanzania) on the 12th November 2007 (ref: NIMR/HQ/R.8a/Vol.IX/633).

Study design
Evaluator-blind randomised controlled non-inferiority trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-operative infection after caesareans

Interventions
Group 1: ampicillin 1000 mg and metronidazole 500 mg intravenous 20 minutes prior to caesarean section
Group 2: ampicillin 1000 mg and metronidazole 500 mg intravenous 20 minutes prior to caesarean section followed by ampicillin 500 mg 8-hourly for two more doses and metronidazole 500 mg 8-hourly for two more doses. After completion of the intravenous (iv) doses the patients will receive oral medication for four days (total 12 doses) of amoxicillin 500 mg and metronidazole 400 mg.

The follow up will be until the patients are discharged: for uncomplicated lower segment caesarean section (LSCS) this will be on day five (in case of pfannenstiel incision) and day seven (in case of median incision). When complications arise, the patient will be followed up longer, until discharge.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The presence of fever, endometritis, urinary tract infection, wound infection or other serious infections (such as pelvic abscess, peritonitis, sepsis).

Timepoint of evaluation is on discharge (see interventions section): an independent doctor will review the wound and score the wound healing and record if any complication arose or additional antibiotics were given.

Key secondary outcome(s))

No secondary outcome measures

Completion date
21/01/2009

Eligibility

Key inclusion criteria
1. Delivery through caesarean section
2. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Use of antibiotics in the last week
2. Known allergy for any of the antibiotics used
3. Greater than 24 hour rupture of membranes
4. Evident infection or fever pre- or during operation

Date of first enrolment
21/01/2008

Date of final enrolment
21/01/2009

Locations

Countries of recruitment
Tanzania

Study participating centre
PO Box 228
Lindi
Tanzania
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Sponsor information

Organisation
Sokoine Regional Hospital (Tanzania)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sokoine Regional Hospital (Tanzania)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration