

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	<input type="checkbox"/> Prospectively registered
Registration date 05/02/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/02/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

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 below to request a patient information sheet (only in Kiswahili)

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 measure

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.

Secondary outcome measures

No secondary outcome measures

Overall study start date

21/01/2008

Completion date

21/01/2009

Eligibility**Key inclusion criteria**

1. Delivery through caesarean section
2. Informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

160

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)

Sponsor details

PO Box 1011

Lindi

Tanzania

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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Sokoine Regional Hospital (Tanzania)

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