

# 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

<b>Submission date</b> 21/01/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/02/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/02/2008	<b>Condition category</b> 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

### Protocol serial number

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 prophylaxis 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