Intraabdominal irrigation at caesarean delivery and infectious morbidity: randomised controlled trial (RCT)

Submission date Recruitment status Prospectively registered 15/05/2005 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 20/09/2005 Completed [] Results [] Individual participant data Last Edited Condition category Record updated in last year Pregnancy and Childbirth 25/08/2009

Plain English summary of protocolNot provided at time of registration

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Study objectives

Intraabdominal irrigation at caesarean delivery and infectious morbidity can modify post operative infectious morbidity.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Obstetrics and gynaecology

Interventions

The patients will be randomised into two groups:

- 1. Intraabdominal irrigation at caesarean delivery after fetal extraction
- 2. No intraabdominal irrigation at caesarean delivery after fetal extraction

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Post operative infectious complications (including post operative fever and/or postoperative endometritis [ACOG definitions])

Secondary outcome measures

Post operative change in hematocrit and hemoglobin

Overall study start date

01/01/2005

Completion date

30/11/2005

Eligibility

Key inclusion criteria

All patients requiring elective or emergency, primary or repeat Caesarean section and planned to have low segment transverse uterine incision with:

- 1. Gestational age >34 weeks
- 2. No fever
- 3. No prelabor rupture of membranes

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

250

Key exclusion criteria

Pregnancy of less than 34 weeks of gestation, intrauterine fetal death, suspected infection, suspected uterine rupture preterm prelabor rupture of membranes of more than 48 hours.

Date of first enrolment

01/01/2005

Date of final enrolment

30/11/2005

Locations

Countries of recruitment

Tunisia

Study participating centre

71, rue Ch Kallala

Sousse Tunisia 4011

Sponsor information

Organisation

Farhat Hached University Teaching Hospital (Tunisia)

Sponsor details

Department of Obstetrics and Gynaecology Farhat Hached University Teaching Hospital Boulevard M. Karoui Sousse Tunisia 4000

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/0059hys23

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Farhat Hached University Teaching Hospital (Tunisia)

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 summaryNot provided at time of registration