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

Submission date
15/05/2005

Recruitment status
No longer recruiting

Registration date
20/09/2005

Overall study status
Completed

Last Edited
25/08/2009

Condition category
Pregnancy and Childbirth

[ ] 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

Contact name
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4011

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
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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 summary

Not provided at time of registration