

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

Submission date 15/05/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/08/2009	Condition category Pregnancy and Childbirth	<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
Dr Samir Hidar

Contact details
71, rue Ch Kallala
Sousse
Tunisia
4011

Additional identifiers

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Post operative change in hematocrit and hemoglobin

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

ROR

<https://ror.org/0059hys23>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Farhat Hached University Teaching Hospital (Tunisia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration