ISRCTN49779257 https://doi.org/10.1186/ISRCTN49779257

A prospective randomised trial on the effect of placental removal method on operative blood loss and on incidence of post-Caesarean section infections

Submission date
12/11/2002

Recruitment status
No longer recruiting

Registration date
12/11/2002

Overall study status
Completed

Last Edited
27/08/2009

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym
DEDIAR (from the French "Delivrance Dirigée versus délivrance Artificielle")

Study objectives
Not provided at time of registration

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Obstetrics and gynaecology

Interventions
Just before entering the operating room for a Caesarean section, the patients will be randomised in two groups:
1. Direct manual placenta extraction group: the obstetrician's hand is introduced into the uterine cavity and the placenta is removed after creating a cleavage plane
2. Spontaneous placenta removal group: the obstetrician applies gentle traction on the umbilical cord until the placenta passes through the uterine incision

Principal participant variables include: maternal age and parity, gestational age, previous caesarean section, duration of labour, duration of ruptured membranes.

Indications for caesarean section include: elective repeat, labour arrest, malpresentation, foetal distress, antepartum hemoglobin, estimated per operative blood loss, endometritis, wound infection, postpartum haemoglobin, postoperative stay.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2002

Completion date
01/01/2003

Eligibility

Key inclusion criteria
All patients requiring elective or emergency Caesarean section with:
1. Gestational age greater than 34 weeks
2. No multiple gestation
3. No placenta praevia

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
302

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2002

Date of final enrolment
01/01/2003

Locations

Countries of recruitment
Tunisia

Study participating centre
71 Rue CH Gallala
H-Sousse
Tunisia
4011

Sponsor information

Organisation
Farhat Hached University Teaching Hospital (Tunisia)

Sponsor details
Boulevard M Karoui
Sousse
Tunisia
4000

Sponsor type
Hospital/treatment centre

Website
http://www.chu-hached.rns.tn/index.html

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2004		Yes	No