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	Recruitment status No longer recruiting	Prospectively registered		
12/11/2002		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
12/11/2002		[X] Results		
Last Edited	Condition category	[] Individual participant data		
27/08/2009	Pregnancy and Childbirth			

Plain English summary of protocol

Not provided at time of registration

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

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