

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	<input type="checkbox"/> Prospectively registered
Registration date 12/11/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/08/2009	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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

Study outputs

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