Blunt versus sharp expansion of the uterine incision at Caesarean delivery: a prospective randomised clinical trial

Submission date Recruitment status Prospectively registered 26/02/2004 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 30/03/2004 Completed [X] Results [] Individual participant data Last Edited Condition category Pregnancy and Childbirth 26/08/2009

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

Protocol serial number N/A

Study information

Scientific Title

Acronym

HYDICI

Study objectives

Not provided at time of registration

Please note that the target number of participants was added as of 26/08/2009.

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 in two groups:

- 1. Blunt expansion of an initial approximately 2 cm incision with obstetrician's fingers
- 2. Sharp expansion of an initial approximately 2 cm incision by cutting scissors

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/12/2001

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 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

01/01/2000

Date of final enrolment

31/12/2001

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Added as of 26/08/2009:

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	01/04/2007		Yes	No