

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

Submission date 26/02/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/03/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/08/2009	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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2000

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

Age group

Adult

Sex

Female

Target number of participants

300

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)

Sponsor details

Department of Obstetrics and Gynaecology
Farhat Hached University Teaching Hospital
Boulevard M. Karoui
Sousse
Tunisia
4000

Sponsor type

University/education

ROR

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

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

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	01/04/2007		Yes	No