ISRCTN34712244 https://doi.org/10.1186/ISRCTN34712244

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

Registration date
30/03/2004

Overall study status
Completed

Last Edited
26/08/2009

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
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
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Boulevard M. Karoui
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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