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Outcome of modified Misgav Ladach (MML) method in first and second time caesarean deliveries

Submission date	Recruitment status	[ ] Prospectively registered
31/01/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/02/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/02/2009	Pregnancy and Childbirth	[ ] Record updated in last year

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
Outcome of modified Misgav Ladach (MML) method in first and second time caesarean deliveries: a non-randomised controlled single-centre trial

Study objectives
Does modified Misgav Ladach (MML) method result in better outcomes in first time caesarean deliveries compared to second time caesarean deliveries?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Istanbul Bakirkoy Maternity and Children's Hospital Ethical Committee, approved on 07/11/2008.

Study design
Non-randomised controlled single-centre trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Caesarean deliveries

Interventions
This trial is taking place at the Istanbul Bakirkoy Maternity and Children's Hospital, Department of Obstetrics and Gynaecology.

Approximately 200 patients will be recruited, 50 patients in each of the following four groups:

Patients who have never had a caesarean operation:
Group 1: Caesarean delivery with the Pfannenstiel method
Group 2: Caesarean delivery with the MML method

Patients who have had a caesarean operation in previous pregnancy:
Group 3: Caesarean delivery with the Pfannenstiel method
Group 4: Caesarean delivery with the MML method

Patient allocation will be carried out as follows:
On Mondays: Patients planned for first time caesarean delivery will be operated with the MML method.
On Tuesdays: Patients planed for first time caesarean delivery will be operated by the Pfannenstiel method. Patients planned for second time caesarean delivery will be operated by the MML method.
On Fridays: Patients planned for second caesarean deliveries will be operated by the Pfannenstiel method.

Total duration of follow-up: 4 weeks after operation

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Surgical outcomes:
1. Operation time
2. Time until delivery of neonate
3. APGAR score
4. Haemoglobin
5. Haematocrit
6. Surgical complications

Secondary outcome measures
Post-operative outcomes:
1. Hospital stay
2. Febrile morbidity
3. Scar complications
4. Infection
5. Post-operative recovery

Secondary outcomes 2 to 5 were assessed 2 and 7 days after caesarean operation. However, patients who experienced any problem were followed-up until resolution of the problem.

Overall study start date
15/11/2008

Completion date
15/02/2009

Eligibility

Key inclusion criteria

1. Term pregnancies >36 weeks of gestation
2. No age limit

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Approximately 200

Key exclusion criteria
1. Intrauterine infection
2. Anaemia (<haematocrit [Htc] %28)
3. Preoperative transfusion
4. Maternal urinary infection
5. Maternal fever (>37.5 Celsius)
6. Use of antibiotics in the last 7 days
7. Placenta previa
8. Abruptio placenta
9. Severe preeclampsi and Hellp syndrome

Date of first enrolment
15/11/2008

Date of final enrolment
15/02/2009

Locations

Countries of recruitment
Türkiye

Study participating centre
Istanbul cad no:95
Istanbul
Türkiye
34750

Sponsor information

Organisation
Istanbul Bakirkoy Maternity and Children's Hospital (Turkey)

Sponsor details
c/o Dr Ali Gedikbasi
Department of Obstetrics and Gynaecology
Istanbul cad no. 95
Bakirkoy
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Sponsor type
Hospital/treatment centre

Website
http://www.bakirkoydogumevi.gov.tr

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Istanbul Bakirkoy Maternity and Children's Hospital, Department of Obstetrics and Gynaecology (Turkey)

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