

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

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

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

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

Study type(s)

Treatment

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 planned 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(s)

Surgical outcomes:

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

Key secondary outcome(s)

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.

Completion date

15/02/2009

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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 preeclampsia 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)

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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes