

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

<b>Submission date</b> 31/01/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/02/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/02/2009	<b>Condition category</b> 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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## 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