

# 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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### Contact details

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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 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 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 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)

**Sponsor details**

c/o Dr Ali Gedikbasi  
Department of Obstetrics and Gynaecology  
Istanbul cad no. 95  
Bakirkoy  
Istanbul  
Türkiye  
34750

**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