

Comparative study of modified Misgav-Ladach and Pfannenstiel-Kerr caesarean techniques

Submission date 18/03/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/04/2009	Condition category Pregnancy and Childbirth	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Comparative study of modified Misgav-Ladach and Pfannenstiel-Kerr caesarean techniques: a randomised controlled trial

Study objectives

Does modified Misgav-Ladach (MML) method result in better outcomes in first time caesarean deliveries compared to Pfannenstiel-Kerr method?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Dr. Lutfi Kirdar Kartal Research and Training Hospital approved on the 26th March 2009 (ref: 8/26.03.2009)

Study design

Randomised controlled single centre trial

Primary study design

Interventional

Secondary study design

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 Dr. Lutfi Kirdar Kartal Research and Training Hospital, Department of Obstetrics and Gynaecology. Approximately 180 patients will be recruited, 90 patients in each of the following two groups:

Group 1: Caesarean delivery with the Pfannenstiel-Kerr method

Group 2: Caesarean delivery with the MML method

Patient allocation will be carried out as follows:

A computer based randomisation will be prepared. The operation type will be printed on identical sheets of paper, which will be put into identical, consecutively numbered sealed opaque envelopes by a non-participating colleague.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Operation time
2. Time until delivery of neonate
3. APGAR score
4. Blood loss
5. Operative complications
6. Number of used sutures

All measured intra-operatively.

Secondary outcome measures

1. Length of hospital stay
2. Wound seroma
3. Wound infection
4. Mobilisation time
5. Visual Analogue Scale score at 6 and 24 hours of the operation
6. Time of bowel restitution

Measured post-operatively at 6 hours, 24 hours and 5 days.

Overall study start date

26/03/2009

Completion date

26/09/2009

Eligibility

Key inclusion criteria

1. Pregnancies greater than 34 weeks of gestation
2. Women between ages of 18 - 45 years
3. First time caesarean section

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

Approximately 180

Key exclusion criteria

1. Previous lower abdominal incision
2. Pregnancies less than 34 weeks of gestation
3. Known severe anaemia
4. Bleeding disorders
5. Intrapartum febrile illness

Date of first enrolment

26/03/2009

Date of final enrolment

26/09/2009

Locations**Countries of recruitment**

Türkiye

Study participating centre

Cihat Saran Sk. Cagdas Apt. No:11/3

Istanbul

Türkiye

34841

Sponsor information**Organisation**

Dr. Lutfi Kirdar Kartal Research and Training Hospital (Turkey)

Sponsor details

c/o M. Murat Naki

Department of Obstetrics and Gynaecology

Istanbul

Türkiye

34000

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/01c2wzp81>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Dr. Lutfi Kirdar Kartal Research and Training Hospital (Turkey) - Department of Obstetrics and Gynaecology

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