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

Submission date 18/03/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/04/2009	**Overall study status** Completed	
Last Edited 21/04/2009	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))

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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration