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Effects of epidural lidocaine analgesia on labor and delivery

Submission date	Recruitment status	[_] Prospectively registered
26/04/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/05/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/01/2007	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8112

Study information

Scientific Title

Study objectives
Epidural analgesia for labor does not affect the duration of the first or second stages of labor

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Kashan University of Medical sciences approved this research on 01/10 /2002, reference number: 8112

Study design
Interventional, randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Labor pain

Interventions
197 women were randomized to receive epidural with bolus doses of 1% lidocaine, 198 women were randomized to receive single-dose intravenous meperidine 25 to 50 mg

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lidocaine, meperidine

Primary outcome measure
Epidural analgesia for labor does not prolong the first or second stages of labor

Secondary outcome measures

Epidural analgesia for labor does not affect neonatal apgar score

Overall study start date
01/06/2004

Completion date
01/02/2005

Eligibility

Key inclusion criteria
1. Nulliparity
2. Active labor
3. Cervical dilatation ≥4 cm
4. Single fetus with vertex presentation
5. American Society of Anesthesiologists (ASA) status 1
6. Request for analgesia

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
395

Key exclusion criteria
1. ASA status >2
2. Age <19 years old
3. Receiving analgesia prior to enrolment
4. Accidental dural puncture
5. Multiparity
6. Probable cephalopelvic disproportion on pelvic examination
7. Cervical dilatation to >4 cm

Date of first enrolment
01/06/2004

Date of final enrolment
01/02/2005

Locations

Countries of recruitment
Iran

Study participating centre
5th Kilometers of Ravand Road
Kashan
Iran
-

Sponsor information

Organisation
Kashan University of Medical Sciences (Iran)

Sponsor details
15 Khordad Square
Setad Markazi Daneshgah
Kashan
Iran
-

Sponsor type
University/education

Website
http://www.kaums.ac.ir

ROR
https://ror.org/03dc0dy65

Funder(s)

Funder type
University/education

Funder Name
Kashan University of Medical Sciences, Iran (8112)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	18/12/2006		Yes	No