Effects of epidural lidocaine analgesia on labor and delivery

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Shahram Nafisi

Contact details

5th Kilometers of Ravand Road Site Maskoni Pezeshkan F1, No. 17 Kashan Iran

Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

Epidural analgesia for labor does not affect neonatal apgar score

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

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Sponsor information

Organisation

Kashan University of Medical Sciences (Iran)

ROR

Funder(s)

Funder type

University/education

Funder Name

Kashan University of Medical Sciences, Iran (8112)

Results and Publications

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