Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Intravenous paracetamol versus intramuscular pethidine in relief of labor pain in primigravid women

Protocol summary

Summary

Aims: to compare vaginal delivery pain score in both groups Methods: In this single-blinded, randomized control trial,61primigravid singleton women with full-term pregnancy candidate for normal vaginal delivery, were entered the trial and divided in to pethedine (A) and paracetamol (B) group.At the time of admission, age and body mass index of mother and gestational age based on last day of period were recorded. In both groups, intramuscular promethasine and hyosine were administered to each patient at the first stage of delivery. Since beginning of active phase of delivery (50 mm of cervical dilatation and 100 % effacement), patients in group A received 50mg intramuscular pethedine injection. At the same time patients in group B, received an intravenous solution infusion containing 1000mg paracetamol and 300 cc of normal saline. After child birth, average labor pain was assessed using Visual Analogue Scale (VAS) by direct questioning from patient in both groups.Apgar score of neonate, duration of labor and incidence of drug complications in 24 hours after delivery were recorded in each group. Primaryout come variable: labour pain score secondary outcome variable: neonate Apgarscore, drug side effects inclusion criteria: primigravid singleton women with fullterm pregnancy (gestational age more than 37 weeks based on ultrasound findings) candidated for normal vaginal delivery exclusion criteria:were history of cardiac, liver and renal disease, anti-convulsive medication consumption, malpresentation of fetus, abnormal fetal monitoring during labor and multiple gestations

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207215506N5**
Registration date: **2012-09-24, 1391/07/03**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2012-09-24, 1391/07/03

Registrant information

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Mohamadhasan Abdollahi
Name of organization / entity
Yazd University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Yazd University of Medical Sciences

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2012-07-05, 1391/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intravenous paracetamol versus intramuscular pethidine in relief of labor pain in primigravid women

Public title

Painless vaginal delivery

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: primigravid singleton women with fullterm pregnancy (gestational age more than 37 weeks based on ultrasound findings) candidated for normal vaginal delivery exclusion criteria:were history of cardiac, liver and renal disease, anti-convulsive medication consumption, malpresentation of fetus, abnormal fetal monitoring during labor and multiple gestations

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Yazd University of Medical Sciences Ethics Committee

Street address
Bahonar sq.

City
Yazd

Postal code

Approval date
2012-02-04, 1390/11/15

Ethics committee reference number
140725

Health conditions studied

1

Description of health condition studied
vaginal delivery with vertex presentation

ICD-10 code
O80.0

ICD-10 code description
Spontaneous vertex delivery

Primary outcomes

1

Description
Labor pain

Timepoint
Immediately after child birth

Method of measurement
Visual analogue scale

Secondary outcomes

1

Description
Neonatal Apgar score

Timepoint
Immediately and 5 minutes after child birth

Method of measurement
Apgar score table

2

Description
Medical complication

Timepoint
24 hours after delivery

Method of measurement
Study questionarie

Intervention groups

1

Description
Since beginning of active phase of delivery (50 mm of cervical dilatation and 100 % effacement), patients in group control received 50mg intramuscular pethedine injection.

Category
Treatment - Drugs

2

Description
Intervention group: Since beginning of active phase of delivery (50 mm of cervical dilatation and 100 % effacement), patients in this group received an intravenous solution infusion containing 1000mg paracetamol and 300 cc of normal saline.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mojibian hospital

Full name of responsible person

Street address
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Hasan Mozaffari
Street address
Bahonar square
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty