

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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, 61 primigravid singleton women with full-term pregnancy candidate for normal vaginal delivery, were entered the trial and divided into pethidine (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 promethazine 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 pethidine 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. **Primary outcome variable:** labour pain score **secondary outcome variable:** neonate Apgar score, 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

Name

Mohamadhasan Abdollahi

Name of organization / entity

Yazd University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1826 0277

Email address

mhabdollahi@ssu.ac.ir

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 questionnaire

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

Yazd University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hassan Abdollahi

Position

Assistant professor of anesthesiology group

Other areas of specialty/work

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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