Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of Pethidine in shortening of first and second stage of labor

Protocol summary

Summary

The goal of this study is investigating the effect of pethidine on reduction of the duration of first and second stages of labor. Inclusion criteria consists of term pregnant women candidate for induction of labor, nulliparity, posterior vertex presentation, age between 18 and 35, healthy, single fetus. Exclusion criteria consists of estimated fetal weight greater than 4 kilograms, suspicion of cephalopelvic disproportion, allergy to pethidine, previous uterine surgery, active vaginal bleeding, placenta previa, use of any kind of analgesia prior to randomization, non-reassuring fetal heart rate tracing, meconium defecation, multiparity, spontaneous labor. The study population includes the term nulliparous pregnant women who are referred to Kosar Hospital for termination of pregnancy. The sample size consists of two groups of 60 peoples. In case group, we inject intravenously 50 milligrams of pethidine as single dose when cervical dilatation reaches to 4-6 centimeters, and in control group, normal saline instead of pethidine. We measure the interval time between injection of pethidine to complete dilatation of cervix, the duration of second stage of labor, the interval time between injection of pethidine to delivery, the rate of caesarean section, determination of first and fifth minute Apgar in the neonates, determination of maternal complications (diminished hemoglobin level 6 hours after delivery and cervical laceration).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012016283N1**
Registration date: **2014-04-14, 1393/01/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-14, 1393/01/25

Registrant information

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Nargesbeygom Hashemian
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Qazvin University of Medical Science
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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for research of Qazvin University of Medical Science

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Pethidine in shortening of first and second stage of labor

Public title

The effect of Pethidine in shortening of first and second stage of labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : term pregnant women candidate for induction of labor; nulliparity; posterior vertex

presentation; age between 18 and 35; healthy; single fetus; Exclusion critria :estimated fetal weight greater than 4 kilograms; suspicion of cephalopelvic disproportion; allergy to pethidine; previous uterine surgery; active vaginal bleeding; placenta previa; use of any kind of analgesia prior to randomization; non-reassuring fetal heart rate tracing; meconium defecation; multiparity; spontaneous labor;

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qazvin University of Medical Science

Street address
Bahonar Blvd , Qazvin

City
Qazvin

Postal code
3419759811

Approval date
2014-03-02, 1392/12/11

Ethics committee reference number
8485

Health conditions studied

1

Description of health condition studied
Delivery

ICD-10 code
O00-O99

ICD-10 code description
Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
duration of first and second phase of labor

Timepoint
during the study

Method of measurement
observation and physical examination

Secondary outcomes

1

Description
caesarean section rate

Timepoint
during the study

Method of measurement
observation

2

Description
the rate of diminished maternal hemoglobin 6 hours after delivery

Timepoint
6 hours after delivery

Method of measurement
hemoglobin level of blood measurement

3

Description
Apgar score

Timepoint
first and fifth minute after delivery

Method of measurement
Apgar score sheet

4

Description
incidence of cervical laceration

Timepoint
during the study

Method of measurement
observation

Intervention groups

1

Description
In the case group, at the time of 4 to 6 centimeters cervical dilatation, we inject a single dose of 50 milligrams Pethidine intravenously.

Category
Treatment - Drugs

2

Description
In control group, we inject intravenously normal saline instead of Pethidine as the same way.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital
Full name of responsible person
Narges Beygom Hashemiyan
Street address
Kosar Hospita, Taleghni street, Qazvin
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research of Qazvin University of Medical Science
Full name of responsible person
Dr Sayed Assefzadeh
Street address
Qazvin University of Medical Science, Shahid Bahonar Blvd , Qazvin City
City
Qazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for research of Qazvin University of Medical Science
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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Person responsible for updating data

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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