Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison the effect of dexamethazone and promethazin with meperidin in rate of nausea and vomiting, labor pain and duration of labor in women with normal vaginal delivery

Protocol summary

Summary

The objective of this study is to compared the effect of dexamethazone and promethazin with meperidin in rate of nausea and vomiting, labor pain and duration of labor in women with normal vaginal delivery. This study, clinical trials, double-blind, placebo- control, single center are conducted in Arash women's hospital. Among women with term singleton pregnancies with normal vaginal delivery (with cervical dilatation 4-5 cm) 60 women will randomly participated in this study. Exclusion criteria included mother's weight less than 50 kg or more than 100 kg, use of epidural anesthesia, drug and alcohol abuse, history of allergy to drugs used in the study and pre-eclampsia. Participants will allocated in two equal groups. Group1: 100 mg meperidin with 2cc normal saline/ IM and 8 m gr dexamethazone/IV will injected.Group2: 100mg meperidin with 50 mgr promethazin/IM and 2 cc normal saline/IV will injected. The patients will interviewed by a blinded investigator for rate of nausea and vomiting, labor pain 0,30,90 and 120 min after intervention and duration of labor will recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406021951N4**
Registration date: **2014-09-17, 1393/06/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-09-17, 1393/06/26

Registrant information

Name

Nasrin Faridi Tazeh-kand

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

nfaridi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of dexamethazone and promethazin with meperidin in rate of nausea and vomiting, labor pain and duration of labor in women with normal vaginal delivery

Public title

Evaluation the effect of dexamethazone and promethazin with meperidin in rate of labor pain and duration of labor in women with normal vaginal delivery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: singleton pregnancy with cephalic

presentation, gestational age 38 to 42 weeks with an uncomplicated vaginal delivery. Exclusion criteria: mother's weight less than 50 kg or more than 100 kg, use of epidural anesthesia, drug and alcohol abuse, history of allergy to drugs used in the study and pre-eclampsia.

Age
From **74 years** old to **52 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Qods St, Keshavarz Blvd

City
Tehran

Postal code

Approval date
2014-11-22, 1393/09/01

Ethics committee reference number
1147/130/93/ص

Health conditions studied

1

Description of health condition studied
Normal vaginal delivery

ICD-10 code
z37.0

ICD-10 code description
Single live birth

Primary outcomes

1

Description
Intensity of labor pain

Timepoint
Before intervention and 30,60,90 and 120 min after intervention

Method of measurement
Visual scale

2

Description
Duration of labor

Timepoint
Before intervention and 30,60,90 and 120 min after intervention

Method of measurement
Timer

3

Description
The Rate of nausea and vomiting

Timepoint
Before intervention and 30,60,90 and 120 min after intervention

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention1:100 mg meperidin with 2cc normal saline/ IM and 8 mgr dexamethazone/IV will injected.

Category
Treatment - Drugs

2

Description
Intervention 2:100mg meperidin with 50 mgr promethazin/IM and 2 cc normal saline/IV will injected.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Arash Women's Hospital

Full name of responsible person

Nasrin Faridi Tazeh-kand

Street address

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse,Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences, Deputy of Research

Full name of responsible person

Dr Yonesian

Street address

Qods St, Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences, Deputy of Research

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

Arash Women 's Hospital, Tehran University of Medical Sciences

Full name of responsible person

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Position

Assistant professor

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