

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 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

+98 21 7788 3283

##### 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**

Dr Nasrin Faridi Tazeh-kand

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

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

**City**

Tehran

**Postal code**

**Phone**

+98 21 7771 9922

**Fax**

**Email**

nfaridi@sina.tums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Arash Women 's Hospital,Tehran University of Medical  
Sciences

**Full name of responsible person**

Dr Nasrin Faridi Tazeh-kand

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

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

**City**

Tehran

**Postal code**

**Phone**

+98 21 7771 9922

**Fax**

**Email**

nfaridi@sina.tums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Arash Women 's Hospital,Tehran University of Medical  
Sciences

**Full name of responsible person**

Dr Nasrin Faridi Tazeh-kand

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

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

**City**

Tehran

**Postal code**

**Phone**

+98 21 7771 9922

**Fax**

**Email**

nfaridi@sina.tums.ac

**Web page address**

## 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*