

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### : Effect of warm shower and intravenous injection of hyoscine on the pain severity and duration of the active phase of labor in primiparous women

#### Protocol summary

##### Summary

**Aims:** Effect of warm shower and intravenous injection of hyoscine on the pain severity and duration of the active phase of labor in primiparous women **Design:** Single-blind randomized clinical trial **Method:** This study will be carried out in 29 Bahman Hospital of Tabriz. The subjects will be randomly assigned into three groups of 54 subjects with block sizes of 3 and 6 using computer software. In order to conceal allocation, the type of intervention will be written on a piece of paper and will be placed inside opaque sealed sequentially numbered envelopes. **Participants:** 162 nulliparous women. **Interventions:** Two intervention groups will receive hot shower and intravenous Hyoscine injection and the control group will receive no intervention. Hot shower will be firstly applied for 20 minutes at 4 cm dilation and then at 7 cm dilation. Also, Hyoscine will be injected at 4 cm dilation and then at 7 cm dilation, 20 mg in ml intravenously and diluted with 5 cc of distilled water. The duration of intravenous injection will be 1 to 2 minutes. Main outcome measures include the pain severity and the duration of active phase that will be measured respectively by Visual Analogue Scale (VAS) and partograph form.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015012610324N22**  
Registration date: **2015-06-05, 1394/03/15**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-06-05, 1394/03/15

#### Registrant information

##### Name

Mojgan Mirghafourvand

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6969

##### Email address

mirghafourvandm@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

#### Expected recruitment start date

2015-04-21, 1394/02/01

#### Expected recruitment end date

2015-08-23, 1394/06/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

: Effect of warm shower and intravenous injection of hyoscine on the pain severity and duration of the active phase of labor in primiparous women

#### Public title

: Effect of warm shower and intravenous injection of hyoscine on the pain severity and duration of the active phase of labor in primiparous women

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Being primiparous; Spontaneous

starting of labor pain; Not suffering from disease; Normal fetal heart rate according to CTG; Cephalic presentation based on ultrasound; Desire to participate in study. Exclusion criteria: Having contraindication of normal delivery; Taking sedative and narcotic drugs during 48 hours prior to entering the study; Mental disorder history according to the patient's expression; Internal-surgical diseases including cardiovascular disease, thyroid disease, liver disease, kidney disease, asthma, epilepsy and etc according to the patient's expression; History of health problems in the current pregnancy according to the patient's expression; Participate in physiological childbirth classes.

#### **Age**

From **15 years** old to **49 years** old

#### **Gender**

Female

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **162**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### 1

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

###### **Street address**

Research Department of Tabriz University of Medical Sciences, Tabriz, Mohammad Reza Rashidi, Liberty Street, St. Golgasht, Tabriz University of Medical Sciences, Central Building No. 2, Third Floor, Research Department of Tabriz Tabriz

###### **City**

Tabriz

###### **Postal code**

##### **Approval date**

2010-09-23, 1389/07/01

##### **Ethics committee reference number**

93165

### **Health conditions studied**

#### 1

##### **Description of health condition studied**

Delivery

##### **ICD-10 code**

O80

##### **ICD-10 code description**

Single spontaneous delivery

### **Primary outcomes**

#### 1

##### **Description**

Labor pain severity

##### **Timepoint**

30 minutes after the intervention

##### **Method of measurement**

Visual Analogue Scale

#### 2

##### **Description**

Duration of active phase of labor

##### **Timepoint**

From 4 cm dilation to full dilation

##### **Method of measurement**

Partograph form in terms of minute

### **Secondary outcomes**

#### 1

##### **Description**

Duration of second stage of labor

##### **Timepoint**

From full dilation until the newborn expulsion

##### **Method of measurement**

Partograph form in terms of minute

#### 2

##### **Description**

Duration of third stage of labor

##### **Timepoint**

From newborn expulsion until placenta expulsion

##### **Method of measurement**

Partograph form in terms of minute

#### 3

##### **Description**

Birth experience

##### **Timepoint**

12 to 24 hours postpartum

##### **Method of measurement**

Birth experience scale

## Intervention groups

### 1

#### Description

The control group will receive no intervention.

#### Category

N/A

### 2

#### Description

The first intervention group will receive hot shower for 20 minutes at 4 cm and 7 cm dilation.

#### Category

Treatment - Other

### 3

#### Description

The second intervention group will receive Hyoscine at 4 cm and 7 cm dilation, 20 mg in ml intravenously diluted with 5 cc of distilled water.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

29 Bahman hospital of Tabriz

##### Full name of responsible person

Safa Madadi

##### Street address

29 Bahman Hospital, Tabriz

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

##### Full name of responsible person

Rashidi Mohammad Reza

##### Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

##### City

Tabriz

##### 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, Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Mojgan Mirghafourvand

##### Position

PhD of Reproductive Health

##### Other areas of specialty/work

##### Street address

Nursing & Midwifery Faculty, South Shariati Street, Tabriz

##### City

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##### Postal code

51745-347

##### Phone

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##### Email

Mirghafourvandm@tbzmed.ac.ir;

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##### Web page address

<http://nursing.tbzmed.ac.ir/>

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Mojgan Mirghafourvand

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PhD of Reproductive Health

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**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Safa Madadi

**Position**

MSc student in Midwifery

**Other areas of specialty/work****Street address**

Nursing & Midwifery Faculty, South Shariati Street,

Tabriz

**City**

Tabriz

**Postal code****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*