

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The effect of intramuscular Hyoscine and Hyoscine-Promethazine on the duration of labour and delivery outcomes to nulliparous pregnant women (triple-blind randomized control trial)

#### Protocol summary

##### Summary

This study has been designed for assessment of effects of Hyoscine and Hyoscine-Promethazine on duration of labor and maternal, fetus and newborn outcomes. In this study our inclusion criteria will be 213 nulliparous women with/without abort in Zanjan hospitals. This study will be triple-blind (blinding of outcome assessor, patients and investigator) and will be three groups. The first group will receive 20mg(1ml) Hyoscine with 2ml distilled water(DW)(total 3ml), the second group 20mg(1ml) Hyoscine with 25mg(1ml) Promethazine+1ml DW(total 3ml) and third group(control group) 3ml DW. Major outcomes will include to duration of active phase of labor(dilatation 4-5cm and effacement 50-60% to full dilation), maternal outcomes (kind of vaginal delivery(operative delivery, epiziotomy with or without rupture) rupture of delivery channel(1-4 degree), cervical laceration and uterine atonia) and fetal outcomes (tachycardia, bradycardia, loss bite to bite variability and deceleration fetal heart rate)

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201512163027N29**

Registration date: **2016-02-07, 1394/11/18**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-02-07, 1394/11/18

##### Registrant information

##### Name

Fahimeh Sehhatie Shafaie

##### Name of organization / entity

Tabriz university of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6770

##### Email address

sehhatief@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2015-12-22, 1394/10/01

##### Expected recruitment end date

2016-04-29, 1395/02/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of intramuscular Hyoscine and Hyoscine-Promethazine on the duration of labour and delivery outcomes to nulliparous pregnant women (triple-blind randomized control trial)

##### Public title

Hyoscine and Hyoscine-Promethazine effects on the delivery

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

37-41 weeks for gestational age; beginning uterus contraction spontaneous; 4-5 for dilatation; 50-60% for effacement; rupture amniotic sac before intervention but

not more than 6h past from its rupture; one twin; nulliparous(with/without abortion in previous pregnancy); lack of problem and sick in this pregnancy(for example preeclampsia, diabet,...); lack of controandication for normal delivery(HSV, CPD, placenta previa,... ); lack of problem in fetuse(unormal presentation); normal BMI in this pregnancy; fetus weight in normal range(2500-4000) according sonography or clinical exam; lack of major hip tightness; cephalic presentation; major height at least 150cm; mather age(18-35) lack of glocome in mather(according to mathers statement); outgoing criteria(sensitivity to Hyoscine, unwillingness to continiue investigation, unormalfetus presentation, epidural analgsia)

**Age**

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

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **213**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Triple blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tabriz medical university

**Street address**

central building, Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz

**City**

tabriz

**Postal code**

5165665931

**Approval date**

2015-12-07, 1394/09/16

**Ethics committee reference number**

TBZMED.REC.1394.833

**Health conditions studied****1****Description of health condition studied**

delivery

**ICD-10 code**

O80.9

**ICD-10 code description**

Single spontaneous delivery, unspecified

**Primary outcomes****1****Description**

Kind of vaginal delivery, rapture of delivery canal without episiatomy, cervical laceration and uterus atonia

**Timepoint**

since begining intervention to 2 hours after birth

**Method of measurement**

check list

**2****Description**

total of first stage of delivery

**Timepoint**

since intervention to birth

**Method of measurement**

timer

**3****Description**

tachycardia, bradycardia, lost of beat to beat variability and long time deseleration in FHR

**Timepoint**

Since intervention to birth

**Method of measurement**

use of CTG

**Secondary outcomes****1****Description**

Total time for second and third stage of delivery

**Timepoint**

since camplet dilatation to delivery and exit plasenta

**Method of measurement**

timer

**2****Description**

1 and 5 appgars, need to revival, the severityof jaundice if admitted to NICU

**Timepoint**

since delivery to releasing mather

**Method of measurement**

check list

### 3

**Description**

giddiness, dizziness, tachycardia, lips dryness, flushing of face, headache, nausea,

**Timepoint**

from intervention to 2 hours after delivery

**Method of measurement**

check list

## Intervention groups

### 1

**Description**

( Ampul Hyoscine 20mg + 2cc distilled water) (total 3cc)

**Category**

Treatment - Drugs

### 2

**Description**

Ampul Hyoscine 20mg(1cc) plus  
Promethazine 25mg(1cc) plus 1 cc distilled water (total 3cc)

**Category**

Treatment - Drugs

### 3

**Description**

distilled water 3 cc

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Amiralmomenin Hospital in Khodabande city

**Full name of responsible person**

Dr Fatemeh Khanmohammadi

**Street address**

Amiralmomenin hospital, Shafa Stret, Khodabande, Zanzan

**City**

Khodabande

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

doc Mohammad Reza Rashidi

**Street address**

Center building of Tabriz Medical University, Golgasht Streat, Azadi Streat, Tabriz

**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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**

Nursing and Midwifery Faculty

**Full name of responsible person**

Farzane Shahmohammadi

**Position**

faculty of midwifery student

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

Emam Streat

**City**

Zanzan

**Postal code****Phone**

+98 24 3422 2280

**Fax****Email**

farzane.shah@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Nursing and Midwifery Faculty

**Full name of responsible person**

Fahime Sehhatie Shaffaee

**Position**

Master degree

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

blinding of Medical and Sciences University, Southern Shriati Streat, Tabriz

**City**

Tabriz

**Postal code****Phone**

+98 41 3477 0648

**Fax**  
**Email** sehatief@tbzmed.ac.ir  
**Web page address**

+98 41 3477 0648  
**Fax**  
**Email**  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Nursing and Midwifery Faculty  
**Full name of responsible person**  
Fahime Sehhatie Shafae  
**Position**  
Master degree  
**Other areas of specialty/work**  
**Street address**  
Bilding of Medical and Sciences University South  
Shariati, Tabriz  
**City**  
Tabriz  
**Postal code**  
**Phone**

## 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*