

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparison of the effect of misoprostol and cervical catheter with oxytocin and cervical catheter in the induction of labor: a clinical trial

#### Protocol summary

##### Study aim

Comparison of the effect of misoprostol and cervical catheter with oxytocin and cervical catheter in the induction of labor

##### Design

This randomized double-blind clinical trial study will be performed on 50 patients undergoing induction of labor with a computer-generated randomization list with a block size of 4, with 1:1 allocation.

##### Settings and conduct

Term pregnant women admitted to al-Zahra and Taleghani hospitals in Tabriz who are candidates for termination of pregnancy through vaginal delivery due to various reasons are included in this study. First, we will take informed written consent and all part of the study will be explained to the patients. The treatment allocation will be placed in a sealed opaque envelope and picked up consecutively.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: term pregnancy, indication for termination of pregnancy, Bishop Score 6 or less, singleton pregnancy, reassuring fetal heart rate, cephalic presentation, intact fetal membranes, ineffective labor contractions, primiparous women exclusion criteria: Misoprostol allergy, fever over 38 °C, history of uterine and cesarean surgery, obstetric induction for cesarean delivery, anemia and blood dyscrasia and asthma

##### Intervention groups

In the misoprostol and catheter group, a no.16 foley catheter is inserted into the cervix and at the same time 25 µg misoprostol is given sub-lingually and if there is no any contraction repeated every 6 hours for up to 4 doses. In the second group, the cervical catheter is inserted and induction begins with oxytocin. In both groups, the Foley catheter balloon is filled with 30 ml of distilled water.

##### Main outcome variables

Time needed to soften and ripen the cervix

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101227005485N8**

Registration date: **2020-04-27, 1399/02/08**

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

Last update: **2020-04-27, 1399/02/08**

Update count: **0**

##### Registration date

2020-04-27, 1399/02/08

##### Registrant information

##### Name

Nazli Navali

##### Name of organization / entity

Tabriz University of Medical Sciences, Faculty of Medicine

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1330 2879

##### Email address

navalin@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2020-08-20, 1399/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effect of misoprostol and cervical catheter with oxytocin and cervical catheter in the induction of labor: a clinical trial

## Public title

Comparison of the effect of misoprostol with oxytocin in companion with a cervical catheter in the induction of labor: a clinical trial

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Pregnancy age of 37 weeks and over indication for termination of pregnancy primiparous women singleton pregnancy reassuring fetal heart rate cephalic presentation intact fetal membranes ineffective labor contractions Bishop Score 6 or below

### Exclusion criteria:

Misoprostol allergy fever over 38 °C history of uterine surgery and cesarean obstetric indication for cesarean delivery anemia and blood dyscrasia asthma

## Age

No age limit

## Gender

Female

## Phase

3

## Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: 50

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The placement in each intervention or control group will be done by the sealed envelopes containing the type of intervention and the envelopes will be removed and opened consecutively, and the type of treatment will be based on its content. This will be done in such a way that the outcome assessor and the data analyzer will not know the intervention type.

## 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

#### Street address

Research Deputy of Tabriz University of Medical Sciences, University of Tabriz, Golgasht street

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

۱۴۴۹۶۱۴۵۳۵

### Approval date

2019-12-24, 1398/10/03

### Ethics committee reference number

IR.TBZMED.REC.1398.984

## Health conditions studied

## 1

### Description of health condition studied

labor induction

### ICD-10 code

### ICD-10 code description

## Primary outcomes

## 1

### Description

The time to ripen the cervix

### Timepoint

every two hours

### Method of measurement

vaginal examination

## 2

### Description

Duration of latent phase of labor

### Timepoint

every two hours

### Method of measurement

vaginal examination

## Secondary outcomes

## 1

### Description

Duration of active phase of labor

### Timepoint

every hour

### Method of measurement

vaginal examination

## 2

### Description

duration of second stage of labor

**Timepoint**

every half hour

**Method of measurement**

vaginal examination

**3**

**Description**

complication rate

**Timepoint**

Continuous during labor

**Method of measurement**

fetal monitoring

## Intervention groups

**1**

**Description**

Control group:Following the insertion of the Foley catheter No.16 inside the uterus and filling its bag with 30 cc of serum saline, 25 micro-gram of misoprostol tablet will be given sub-lingually and repeated every 6 hours for up to 4 doses in the absence of effective labor contractions. If spontaneous contractions occur for at least 3 contractions of 45-60 seconds within 10 minutes, the next dose will not be given. Upon dilatation of 3-4 cm, if no contraction occurs, induction will begin with high dose oxytocin (4 mili-unit per minute every 15-20 minutes will be done and this will be continued until at least 3-4 contractions of 45-60 seconds occur every 10 minutes) method.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: Following the insertion of the Foley catheter No.16 inside the uterus and filling its bag with 30 cc of serum saline, induction with high dose method, 4 mili-unit per minute of oxytocin and increment of 4 mili-unit per minute every 15-20 minutes will be done and this will be continued until at least 3-4 contractions of 45-60 seconds occur every 10 minutes.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Alzahra and Taleghani Hospitals

**Full name of responsible person**

Dr. Navali Nazli

**Street address**

South Artesh Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138665793

**Phone**

+98 41 3554 1221

**Email**

navalin@tbzmed.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Laya Farzadi

**Street address**

South Artesh Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138665793

**Phone**

+98 41 3554 1221

**Email**

navalin@tbzmed.ac.ir

**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**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Nazli Navali

**Position**

infertility fellowship/associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Alzahra hospital, Artesh street

**City**

Tabriz

**Province**

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**Postal code**

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**Email**

navalin@tbzmed.ac.ir

## Person responsible for scientific inquiries

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Nazli Navali

**Position**

associate professor/infertility fellowship

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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Artesh street, Alzahra Hospital

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Tabriz

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5138665793

**Phone**

+98 41 3554 1221

**Email**

navalin@tbzmed.ac.ir

## Person responsible for updating data

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Nazli Navali

**Position**

associate professor/infertility fellowship

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Part of the data will be published as an article.

**When the data will become available and for how long**

2 years

**To whom data/document is available**

The data will be accessible to anyone interested in the field.

**Under which criteria data/document could be used**

for utilization in researches like in meta-analyses

**From where data/document is obtainable**

The applicants can mail their request to the person responsible for scientific inquiries or by referring to Women's Health Research Center, Al-Zahra Hospital, Artesh street in Tabriz, they ask the scientific staff to study the data and mention their motives.

**What processes are involved for a request to access data/document**

After requesting the data via email, after reviewing the motivation and purpose of the request, the data will be made available to the applicant.

**Comments**