

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Efficacy and side effects of transcervical catheter and vaginal Misoprostol on cervical ripening

#### Protocol summary

##### Summary

When labor induction is indicated for women with unripe cervix and oxytocin induction alone will not be answered, there is several choices for ripening of cervix with low bishop score. Transcervical catheter and misoprostol are kinds of them. This research will compare benefits and disadvantages of this two procedures. Term pregnant women with indication of delivery and low bishop score of cervix divide to same 60 groups of getting misoprostol or transcervical catheter and then evaluate time of ripening of cervix, c/s rate, and other disadvantages such as meconium in amniotic fluid.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201012225448N1**  
Registration date: **2011-05-04, 1390/02/14**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-05-04, 1390/02/14

##### Registrant information

##### Name

Fateme Mallah

##### Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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#### Recruitment status

##### Recruitment complete

##### Funding source

Tabriz University Of Medical Sciences, Research  
Chancellory

##### Expected recruitment start date

2010-10-23, 1389/08/01

##### Expected recruitment end date

2011-10-23, 1390/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy and side effects of transcervical catheter and vaginal Misoprostol on cervical ripening

##### Public title

The comparison of drug and mechanical methods for cervical ripening before delivery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: gestational age over 37 weeks, singleton gestation, cephalic presentation, intact amnion sac, not contraindication of misoprostol use, first gravity, 3 to 4 bishop score  
Exclusion criteria: allergy to misoprostol, elective cesarean section, urgent delivery by c/s, IUGR, placenta previa, fetal bradycardia, placental abruption, massive bleeding, placenta previa and previous cesarean section.

##### Age

From **15 years** old to **45 years** old

##### Gender

Female

##### Phase

N/A

#### Groups that have been masked

No information

### Sample size

Target sample size: **120**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tabriz University Of Medical Sciences,Vice chancellor  
for Research

##### Street address

Third Floor, Central Building of Number2, Golgasht  
Street

##### City

Tabriz

##### Postal code

##### Approval date

2010-10-09, 1389/07/17

##### Ethics committee reference number

5/4/6866

## Health conditions studied

### 1

#### Description of health condition studied

Ripening Of Cervix

#### ICD-10 code

O60-O75

#### ICD-10 code description

Complications of labour and delivery

## Primary outcomes

### 1

#### Description

Ripening of cervix

#### Timepoint

in the time of intervention

#### Method of measurement

bishop score

## Secondary outcomes

### 1

#### Description

Meconium In Amnionic Fluid

#### Timepoint

at time of intervention

#### Method of measurement

Clinical

### 2

#### Description

Uterine Hyperstimulation

#### Timepoint

at time of intervention

#### Method of measurement

clinical

### 3

#### Description

Rupture of uterin

#### Timepoint

at time of intervention

#### Method of measurement

clinical

### 4

#### Description

Result in c/s

#### Timepoint

at time of intervention

#### Method of measurement

Clinical

### 5

#### Description

Fetal Bradycardia

#### Timepoint

In the time of intervention

#### Method of measurement

Clinical

## Intervention groups

### 1

#### Description

Misoprostol 25 microgram per 8 hour until 3 doses will be used in 60 patients with the cervix bishop score 3 or 4. Then duration time to reach 8 bishop score will be measured.

#### Category

Treatment - Other

### 2

#### Description

On the other 60 ones with cervix bishop score of 3or4,

transcervical catheter will be used. time of receiving to cervix bishop score of 8 will be evaluated.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Taleghani Hospital-Tabriz and Alzahra Hospital Tabriz

**Full name of responsible person**

Dr.Fatemeh Mallah

**Street address**

Taleghani Hospital, Rah Ahan Square

**City**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University Of Medical Sciences, Vice chancellor for Research

**Full name of responsible person**

Dr. Alireza Ostad Rahimi

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**City**

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**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, Vice chancellor for 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**

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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*