

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Comparison of the combined effect of Isosorbide with Misoprostol and Misoprostol alone on the cervical ripening in post-term pregnancy

#### Protocol summary

##### Study aim

The purpose of this study was to determine the combined effect of Isosorbide with Misoprostol and Misoprostol alone on cervical ripening in post-term pregnancy.

##### Design

This randomized double-blind controlled trial phase 2 was conducted on 150 primiparous women with singleton pregnancy and Bishop score less than 6 at the Ayatollah Rouhani Hospital in Babol. Women were randomly divided into two groups.

##### Settings and conduct

This study was conducted on all post-term pregnancy need induction of labor in the maternity hospital of Ayatollah Rouhani in Babol in October 2017.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: post-term pregnancy from 18 to 40 years old, Bishop Score 6 and less with a range score of 0 to 13, Body mass index in the first trimester of pregnancy in the normal range (19.8 - 26 kg/m<sup>2</sup>), 41 weeks pregnancy based on ultrasonography of the first trimester of pregnancy, Singleton and cephalic pregnancy, Having a normal fetal heart rate or proper biophysical in 48 hours before entering the study .  
Exclusion criteria: Pregnant women with a history of headache, Misoprostol contraindications, Alcohol consumption, Preeclampsia and eclampsia, Uncontrolled Diabetes, Intrauterine growth restriction, Polyhydramnios and oligohydramnios, Placenta previa or any other factor that prevents the induction of labor.

##### Intervention groups

In the intervention group, isosorbide tablet (Isocor Tablets, 40 mg, Aria Pharmacy) and in the control group, placebo placed vaginally in the posterior fornix, vagina by the senior gynecology resident. Then 24 hours later in both groups, after re-establishing a Bishop: 25 micrograms vaginal misoprostol (mcg, P.I.C, High Wycombe, England) are placed in the posterior fornix, vagina.

#### Main outcome variables

Time to fully cervical ripening for delivery

#### General information

##### Reason for update

Data sharing, revising title, clarifying the inclusion and exclusion criteria, and adding some secondary outcomes, a better description of randomization

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180922041083N1**

Registration date: **2018-12-27, 1397/10/06**

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

Last update: **2021-01-24, 1399/11/05**

Update count: **1**

##### Registration date

2018-12-27, 1397/10/06

##### Registrant information

##### Name

Shahnaz Barat

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3222 7667

##### Email address

sh.barat@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2018-09-23, 1397/07/01

##### Actual recruitment start date

2018-04-06, 1397/01/17  
**Actual recruitment end date**  
2019-05-05, 1398/02/15  
**Trial completion date**  
2019-08-06, 1398/05/15

#### Scientific title

Comparison of the combined effect of Isosorbide with Misoprostol and Misoprostol alone on the cervical ripening in post-term pregnancy

#### Public title

Effect of Isosorbide with Misoprostol on the cervical ripening

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Pregnant mothers from 18 to 40 years old Bishop Score 6 and less with a range score of 0 to 13 Body mass in the first trimester of pregnancy in the normal range (26 - 19.8 kg . m<sup>2</sup>) 41 weeks pregnancy based on ultrasonography of the first trimester of pregnancy Singleton and cephalic pregnancy Having a normal fetal heart rate or proper biophysical in 48 hours before entering the study

##### Exclusion criteria:

Pregnant women with a history of headache Misoprostol contraindications Alcohol consumption Preeclampsia and eclampsia Uncontrolled diabetes Intrauterine growth restriction Polyhydramnios and oligohydramnios Placenta previa or any other factor that prevents the induction of labor Interaction medicine with Isosorbide

#### Age

From **18 years** old to **40 years** old

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

- Participant
- Outcome assessor

#### Sample size

Target sample size: **150**

Actual sample size reached: **150**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization is done using the randomization.com website. The size of blocks will be 8

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The Isosorbide and placebo tablets, which are very similar in appearance, are located in two containers A and B. The resident of obstetrics that aware of the allocation will be given to patients (not aware) based on a randomized block size number. Staff is aware of the drug doses of both containers. The resident will transfer the data checklist to the outcome assessor that is not aware of allocation.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Babol University of Medical Sciences

##### Street address

Babol University of Medical Sciences, Ganj Afrouz Avenue

##### City

Babol

##### Province

Mazandaran

##### Postal code

4716681451

#### Approval date

2018-08-20, 1397/05/29

#### Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.122

## Health conditions studied

### 1

#### Description of health condition studied

Vaginal Delivery

#### ICD-10 code

O80.0

#### ICD-10 code description

Spontaneous Vertex Delivery

## Primary outcomes

### 1

#### Description

the time interval between administration of the first dose of Isosorbide until the cervix is fully ripened and dilated (hours)

#### Timepoint

the time interval between administration of the first dose of Isosorbide until the cervix is fully ripened and dilated (hours)

#### Method of measurement

Yaginal examinatin by Hours

## Secondary outcomes

### 1

#### **Description**

The time interval between administration of the first dose of Isosorbide until delivery of the neonate

#### **Timepoint**

From administration of the first dose of Isosorbide until delivery of the neonate

#### **Method of measurement**

Hours

### 2

#### **Description**

the effect of Isosorbide on the Bishop score 24 hours after administration of Isosorbide

#### **Timepoint**

24 hours after administration of Isosorbide To delivery

#### **Method of measurement**

Bishop Score Scale

### 3

#### **Description**

The effect of Isosorbide on the number of Misoprostol used during labor

#### **Timepoint**

24 hours after intervention to delivery

#### **Method of measurement**

Number Of misoprostol suppository

## **Intervention groups**

### 1

#### **Description**

In the Intervention group, Isosorbide tablets (Isocor Tablet, 40 m, Aria Pharmacy) are used vaginally. Then 24 hours later, after re-establishing a bishop: 25 microgram vaginal misoprostol (P.I.C, High Wycombe, England) is placed in the posterior fornix of the vagina.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

In the control group, the placebo is placed by the senior resident of gynecology in the posterior fornix of the vagina, and 24 hours later, after re-establishing a bishop, 25 microgram vaginal misoprostol (P.I.C, High Wycombe, England) are placed in the posterior fornix of the vagina.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Ayatollah Rouhani Hospital Babol

##### **Full name of responsible person**

Dr. Shanaz Barat

#### **Street address**

Ayatollah Rouhani Hospital in Babol, Ganj Afrooz Avenue,

#### **City**

Babol

#### **Province**

Mazandaran

#### **Postal code**

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#### **Phone**

+98 11 3222 7667

#### **Email**

shahnaz-barat200@yahoo.com

#### **Web page address**

<http://www.mubabol.ac.ir/>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Babol University of Medical Sciences

##### **Full name of responsible person**

Dr. reza Ghadimi

##### **Street address**

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rezaghadimi@yahoo.com

##### **Web page address**

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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**

Babol 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**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Shahnaz Barat

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Mobina Baes

**Position**

Resident of Obstetrics and Gynecology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Shahnaz Barat

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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## Sharing plan

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

Yes - There is 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**

Yes - There is a plan to make this available

**Informed Consent Form**

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

**Clinical Study Report**

Undecided - It is not yet known if there will be 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**

Primary outcome and some secondary outcomes are available to be shared.

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

starting 6 months after publication

**To whom data/document is available**

available for people working in academic institutions and can also apply to receive it.

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

Use in systematic review and meta-analysis studies is permitted

**From where data/document is obtainable**

The data mentioned by the request will be available through my academic email.sh.barat@mubabol.ac.ir

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

6 months after the results are published, the data

mentioned will be available by my email.  
**Comments**