Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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/m2), 41 weeks pregnancy based on ultasonography 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
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Iran (Islamic Republic of)
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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 . m2) 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

Vaginal 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
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Ayatollah Rouhani Hospital in Babol, Ganj Afrooz Avenue,
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Sponsors / Funding sources

1

Sponsor
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
sharting 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