

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Labor induction with unfavorable cervix; Assessing the effect of cervical ripening balloon and evening primrose oil comparing with misoprostol on bishop score and duration of first stage of labor

Protocol summary

Study aim

To determine the effect of cervical ripening balloon and evening primrose oil comparing with misoprostol on bishop score and duration of first stage of labor

Design

A double blind randomized controlled trial with three parallel arms

Settings and conduct

In the labor ward of selected hospitals, If clients are eligible, an informed written consent will be obtained, then, Bishop's checklist will be completed. Participants will be allocated to 3 groups by stratified randomized blocking method with block sizes of 3 and 6 with a 1: 1: 1 allocation ratio including 1: 25 µg of vaginal misoprostol, 2: 4000 mg vaginal capsule of evening primrose oil and 3: Cervical Ripening Balloon. For allocation concealment, the type of intervention will be written on piece of paper and placed inside the sequentially numbered envelopes.

Participants/Inclusion and exclusion criteria

The participants will be women with single and uncomplicated pregnancy, 40 weeks or more gestational age with indications of labor induction, cephalic presentation and Bishop's score less than 4.

Intervention groups

Intervention group 1: 25 micrograms vaginal misoprostol; Intervention group 2: 4000 milligrams vaginal cap evening primrose oil and Intervention group 3: Double balloon Ripping catheter

Main outcome variables

The Bishop score and duration of first stage of labor will be considered as main outcome variables.

General information

Reason for update

The start date of sampling at the time of trial registration was mistakenly recorded as 2020/6/21, which was one

day before registration and showed the research retrospective, while the research was prospective and the actual sampling started 6 months later than study registration in 2020/12/4.

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N56**

Registration date: **2020-06-22, 1399/04/02**

Registration timing: **prospective**

Last update: **2023-03-11, 1401/12/20**

Update count: **1**

Registration date

2020-06-22, 1399/04/02

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-03-17, 1399/12/27

Actual recruitment start date

2020-12-04, 1399/09/14

Actual recruitment end date

2021-12-20, 1400/09/29

Trial completion date

empty

Scientific title

Labor induction with unfavorable cervix; Assessing the effect of cervical ripening balloon and evening primrose oil comparing with misoprostol on bishop score and duration of first stage of labor

Public title

Assessing the effect of cervical ripening balloon and evening primrose oil comparing with misoprostol on bishop score and duration of first stage of labor

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Gestational age \geq 40 weeks Vertex presentation Parity \leq 4 Single pregnancy Lack of vaginal delivery contraindication Uncomplicated pregnancy Bishop score less than 4 Favorable non stress test in admission Lack of effective uterine contractions (less than three contractions in 30 minutes) Intact amniotic sac

Exclusion criteria:

Amniotic fluid volume Disorders Intra Uterine Growth Retardation Fetal macrosomia Any contraindication for evening primrose oil use such as history of seizures in the mother or use of anticonvulsant drugs Contraindication for labor induction High risk pregnancy Existence of chronic or systemic disease such as diabetes and hypertension Existence of scar on the uterus

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated to 3 groups by stratified randomized blocking method (stratification will be based on parity, primiparous in one strata and parity 2 - 4 in another strata) with block sizes of 3 and 6 with a 1: 1: 1 ratio as follows: Group 1: 25 μ g of vaginal misoprostol, Group 2: 4000 mg Vaginal capsule of evening primrose oil (EPO) and Group 3: Cervical Ripening Balloon. for Allocation Concealment, the type of intervention will be written on piece of paper and placed inside the serial numbered envelopes. After obtaining informed consent, the relevant envelope will be opened and the intervention will be performed.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind the drugs, two envelopes with the same content will be prepared for each participant, which will contain 4 capsules (EPO or Placebo capsules) and one tablet (Misoprostol or Placebo) and will be packaged in the same way. Envelopes will be coded by another person. About cervical Ripening Balloon, there is no possible for blinding.

Placebo

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 Sciences

Street address

Research department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2020-05-26, 1399/03/06

Ethics committee reference number

IR.TBZMED.REC.1399.141

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

Labor induction

ICD-10 code

O83.8

ICD-10 code description

Other specified assisted single delivery

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

Bishop score

Timepoint

Before intervention and every 4 hours after intervention until 12 hours

Method of measurement

Bishop scoring scale

2

Description

Duration of first stage of labor

Timepoint

From beginning of induction until childbirth

Method of measurement

Partograph

Secondary outcomes

1

Description

Duration of second stage of labor

Timepoint

After full dilatation

Method of measurement

Partograph

2

Description

Duration of third stage of labor

Timepoint

After neonatal delivery until deliver the placenta

Method of measurement

Partograph

3

Description

Type of delivery (cesarean section rate)

Timepoint

After delivery

Method of measurement

Researcher's designed form

4

Description

First and fifth minute Apgar score

Timepoint

After delivery

Method of measurement

Baby profile sheet

5

Description

Use of oxytocin for labor induction

Timepoint

During labor

Method of measurement

Partograph and labor process improvement sheet

6

Description

Mean score of birth satisfaction

Timepoint

12- 24 hours after delivery

Method of measurement

Birth Satisfaction Scale- revised (BSS-R)

7

Description

Side effects

Timepoint

During labor and after delivery

Method of measurement

Researcher's designed form

Intervention groups

1

Description

Intervention group 1: vaginal capsule evening primrose oil 4000 mg

Category

Treatment - Drugs

2

Description

Intervention group 2: Double balloon cervical ripening catheter

Category

Treatment - Devices

3

Description

Intervention group 3: vaginal tablet misoprostol 25 microgram

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Shahla Hemmatzadeh

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Alzahra Hospital, Artesh street

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2

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Shahla Hemmatzadeh

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3

Recruitment center

Name of recruitment center

29 Bahman Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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mirghafourvandm@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

Shahla Hemmatzadeh

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mojgan Mirghafourvand

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The results of clinical study will be published as article

When the data will become available and for how long

Immediately after publishing the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific using with citation to article

From where data/document is obtainable

mirghafourvandm@tbzmed.ac.ir

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

Up to one week after communication by email

Comments

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mojgan Mirghafourvand

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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