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 baloon 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 Baloon. 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 miligrams 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

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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 baloon 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≥ 40 weeks Vertex presentation Parity ≤ 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 µg of vaginal misoprostol, Group 2: 4000 mg Vaginal capsule of evening primrose oil (EPO) and Group 3: Cervical Ripening Baloon. 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 Baloon, 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
Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue

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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
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Alzahra hospital
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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
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

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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
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