

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparing the Effects of Vaginal Misoprostol, Vaginal Trinitroglycerin (TNG) and oral Evening Primrose Oil in Cervical Ripening at term pregnancy

Protocol summary

Study aim

Comparison of the effect of misoprostol, vaginal nitroglycerine and capsule of evening primrose evening on cervical ripening in the term pregnancy in Shahid Sayyad Shirazi Hospital in Gorgan

Design

A clinical trial with a control group, with two groups of parallel intervention, a single-blind, randomized, random block method with a sample size of 201

Settings and conduct

All pregnant women referring to Sayyad-e-Shirazi Hospital of Gorgan, Iran, were studied by single-blind method and the consequences of this study were measured before and 4 hours after prescribing medications. Measurement of the consequences is performed by gynecology resident who is not informed about intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Pregnant women (primigravid) -Term pregnancy (40 weeks onwards) -Bishop Score less than or equal to 4 -A candidate for induction of childbirth
Exclusion criteria: History of past uterine surgery -Use of intrauterine contraceptives (IUD) -Any medicinal allergy • Developing systemic and localized infection • Developing known diseases such as diabetes, hypertension and... - Existence of any uterine abnormalities.

Intervention groups

Intervention Group (A): Vaginal nitroglycerin 400 mg of Zahravi company, a dose of 4 to 6 hours to 3 is administered. Intervention Group (B): Evening primrose Capsules, 1000 mg capsules of primroses (Barij Essence Company with food and drug verification) in a vaginal form every 4 to 6 hours maximum up to 3 doses The control group (C): 25 mcg of a misoprostol tablet (one-quarter of 100 microgram tablets, Abhan Pharmacy) after humidifying the distilled water every 4to6 hours in vaginal form, maximum of 3 doses

Main outcome variables

Changes in cervix with Bishop score, newborn Apgar score in one and five minutes, length of time from drug to birth, drug side effects, vaginal bleeding rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191115045453N1**

Registration date: **2019-12-12, 1398/09/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-12, 1398/09/21**

Update count: **0**

Registration date

2019-12-12, 1398/09/21

Registrant information

Name

sanaz alizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3225 1502

Email address

sanazalizadehmd@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-06, 1398/09/15

Expected recruitment end date

2020-01-05, 1398/10/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the Effects of Vaginal Misoprostol, Vaginal Trinitroglycerin (TNG) and oral Evening Primrose Oil in Cervical Ripening at term pregnancy

Public title
Comparing the Effects of Vaginal Misoprostol, Vaginal Trinitroglycerin (TNG) and oral Evening Primrose Oil in Cervical Ripening at term pregnancy,

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women (primigravid) the term pregnancy (40 weeks onwards) Bishop Score less or equal to 4 candidate for induction of childbirth
Exclusion criteria:
History of past uterine surgery Use of intrauterine contraceptives (IUD) Any medicinal allergy Developing systemic and localized infection Developing known diseases such as diabetes, hypertension and... Existence of any uterine abnormalities.

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **201**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants were randomly assigned to intervention (A) and Control (B) groups in the study by Block Randomization . That is, by using a dice that has 6 funds, samples are assigned to their groups on any form, and each number is assigned to one of the table blocks, which shows its own state. Group A (vaginal nitroglycerin) and group B (edible capsule primrose evening) and group C (vaginal misoprostol). The complete list of random blocks was presented to the principal researcher by the Epidemiological advisor of the study.

Blinding (investigator's opinion)
Single blinded

Blinding description
The implementation of this study is a blind one (single blinding). In this study, the assessments of the consequences of the study are blind. So that the principal investigator prescribed the drug and the type of group is informed, but the assessment of the consequences for gynecology resident is not in the

current purpose of the study and the type of drugs prescribed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Golestan University of Medical Sciences
Street address
central organization of Golestan University of Medical Sciences, Hirkan Drive, Gorgan
City
Gorgan
Province
Golestan
Postal code
4918936316

Approval date
2019-10-09, 1398/07/17

Ethics committee reference number
IR.GOUMS.REC1398.220

Health conditions studied

1

Description of health condition studied
pregnancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
cervical ripening according to Bishop Score

Timepoint
Before and after 4 hours of intervention

Method of measurement
Bishop's rating table (between 0 and 13)

2

Description
Baby Apgar Score

Timepoint
Minutes One and 5

Method of measurement
Apgar Scoring System (0 to 10)

3

Description

duration of prescribing medications to childbirth

Timepoint

Time of prescription medication and delivery time

Method of measurement

Based on minutes

4

Description

Drug side effects

Timepoint

Prescribed time of medication and 4 hours after drug Administration

Method of measurement

Nausea, vomiting, vaginal bleeding, fever and chills, blurred vision, diarrhea, feeling of bitter taste in the mouth, vaginal pain

5

Description

Vaginal bleeding rate

Timepoint

Postpartum

Method of measurement

It will be measured with a scale of zero to 3 (= 0 = no bleeding, 1 = bleeding), 2 = Low menstrual bleeding, 3 = severe bleeding with clot excretion.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group A Pearl TNG Vaginal 400 mg construction of Zahravi company will be prescribed a dose of 4 to 6 hours to 3.

Category

Treatment - Drugs

2

Description

Intervention group: In group B, the capsule of evening primrose evening, 1000 mg capsules of primroses (Barij Essence Company with food and drug verification) will be given every 4 to 6 hours maximum of 3 doses.

Category

Treatment - Drugs

3

Description

Control group: 25 MCG of a misoprostol tablet (a quarter of 100 microgram Mizotak tablets, pharma Abhan) after humidifying the distilled water, every 4th6 hours in a

vaginal form will be administered to 3 doses

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sayyad Shirazi Education and treatment center

Full name of responsible person

sanaz alizadeh

Street address

Sayyad Shirazi Boulevard

City

gorgan

Province

Golestan

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4917867439

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+98 17 3220 2291

Email

infosayyad@goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohammad Reza Honarvar

Street address

Health Technology Development Center, the second floor, Library building, Golestan University of Medical Sciences, philosophical complex, 5th km of Sari-Gorgan

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Province

Golestan

Postal code

4934174515

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Email

Roshd.center@goums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Sanaz Alizadeh

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 3, Alborz St., Ghaemshahr ., Mazandaran, Iran

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

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Position

resident

Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about the original outcome, or the possibility of sharing.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Only for researchers working in academic and academic institutions

Under which criteria data/document could be used

metanalysis and systematic review

From where data/document is obtainable

investigator through e-mail:
sanazalizadehmd@gmail.com

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

After receiving the email by the researcher, within 14 business days, the application will be examined and the documentation is provided to the applicant.

Comments

