Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Postal code
4917867439
Phone
+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
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3242 4377
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
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Person responsible for updating data

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Postal code
4765694769
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0098173224477
Email
sanazalizadehmd@gmail.com

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