Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effectiveness of vaginal dexamethasone and placebo in preparing the cervix for induction of labor in primiparous pregnant women

Protocol summary

Study aim
Determining the effectiveness of vaginal dexamethasone and placebo in preparing the cervix for induction of labor in primiparous pregnant women referred to Ali-Ebne-Abitaleb hospital in Zahedan during 2025-2026

Design
Clinical trial with intervention and control groups, triple-blind, randomized block design (4-way permutation-stratified), phase 2-3, sample size 100

Settings and conduct
Triple-blind randomized clinical trial in Ali ibn Abi Talib Hospital, Zahedan Number of participants: 100 patients (two groups of 50 each) Groups: Intervention: Vaginal dexamethasone tablet (Tablet A) Comparison: Vaginal placebo (Tablet B) Blinding: The patients, researchers, and research staff are all blinded.

Participants/Inclusion and exclusion criteria
All pregnant mothers referred to the Women's Triage Unit of Ali Ibn Abi Taleb Hospital, Zahedan. Inclusion criteria: Primiparous pregnant mother, singleton pregnancy, age between 18 and 35 years Exclusion criteria: The pregnant woman has used any hormones or medications during her pregnancy. If the pregnant woman has previously referred with immobility/decreased fetal movements or a history of maternal bleeding

Intervention groups
The intervention group consisted of nulliparous pregnant women who received vaginal dexamethasone tablets (Tablet A). The comparison group consisted of nulliparous pregnant women who received vaginal placebo (Tablet B).

Main outcome variables
Bishop score; Apgar score at first minute of the newborn; Apgar score at fifth minute of the newborn

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250118064418N1**
Registration date: **2025-03-01, 1403/12/11**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-01, 1403/12/11**
Update count: **0**

Registration date
2025-03-01, 1403/12/11

Registrant information

Name
setareh jami

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 915 763 6126

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setarehjami9111@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-08, 1403/11/20

Expected recruitment end date
2025-06-10, 1404/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of vaginal dexamethasone and placebo in preparing the cervix for induction of labor in primiparous pregnant women

Public title
Efficacy of vaginal Dexamethasone in cervical preparation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Primiparous pregnant mother singleton pregnancy full pregnancy (37 weeks and 6 days and more) age between 18 and 35 years normal body mass index 18.5 to 24.9 the fetus must be in cephalic position Bishop's score ≤4 estimated fetal weight of 2500-4000 grams the gynecologist and obstetrician make the patient a candidate for termination of pregnancy

Exclusion criteria:
If the pregnant woman use any hormones or herbal medicines (traditional medicines), herbal/natural products, or conventional/prescribed medicines during her pregnancy Those with the following pre-existing conditions, including diabetes, high blood pressure, a history of obstetric complications such as preeclampsia or eclampsia, or HELLP syndrome (hemolysis, elevated liver enzymes, and low platelets) Those with a previous presentation with fetal inactivity/decreased fetal movements Those with a previous presentation with a history of maternal hemorrhage

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
1. Randomization method and description of each method Type of randomization: Block randomization with blocks of four was used in this study 2. Randomization unit Individual randomization: Subjects are entered into the study individually based on patient referrals and are assigned to intervention and control groups through block randomization. 3. Stratified randomization layers If it is necessary to control the effect of intervening variables (such as age, sex, and underlying diseases), stratified randomization is used to perform randomization in each layer in such a way that the balance between groups is maintained regarding important variables. 4. Randomization tool and method of constructing random sequences: It will be using SPSS software. Number of samples: Finally, 50 subjects were placed in the intervention group and 50 subjects in the control group to maintain balance in the sample size.

Blinding (investigator's opinion)
Triple blinded

Blinding description
After enrollment, patients, investigators, and research staff are blinded. Dexamethasone and placebo tablets of the same shape and size, labeled Tablet A and Tablet B, are dispensed by a non-interventionist in the study. Research staff are blinded to the allocation of study drug tablets.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences

Street address
Khalij -e- Fars Blvd

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743175

Approval date
2024-10-16, 1403/07/25

Ethics committee reference number
IR.ZAUMS.REC.1403.287

Health conditions studied

1

Description of health condition studied
Induction of labor with dexamethasone

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Cervical preparation rate for labor induction in primiparous pregnant mothers

Timepoint
During labor, the first minute, and the fifth minute after

delivery

Method of measurement

Cervical preparation dosage form for labor induction

Secondary outcomes

1

Description

Newborn Apgar score

Timepoint

The first and fifth minutes after birth

Method of measurement

The Apgar score, also known as APGAR, is an acronym for 5 criteria that are each examined separately: Skin color (Appearance), Pulse or heart rate (Pulse), Reflex reactions (Grimace), Muscle tone or consistency (Activity), and Respiration.

2

Description

Bishop Score

Timepoint

The initial visit of the pregnant woman and entry into the study and during delivery

Method of measurement

Based on 5 components of dilation, effacement, consistency, cervical position, and organ position, demonstrated through pelvic examination, each of which is given a score from 0 to 3.

Intervention groups

1

Description

Intervention group: Dexamethasone tablets labeled as Tablet A are delivered by a non-interventionist in the study. Dexamethasone is administered in the amount of 8 mg in the form of 2 Dexamethasone tablets (4 mg, from a single company (Obeidi Company) and specified) every 6 hours and vaginally in group A. According to the study protocol, an obstetrician and gynecologist will prescribe the tablets. Vaginal tablets are given to primiparous patients from the onset of labor pains and it is recommended to use 2 tablets every 6 hours and vaginally. If possible, do not move for at least 2 hours after using the tablet. Also, to ensure the use of the tablet, a daily registration form is given to the participants to record each time the tablet is used.

Category

Treatment - Other

2

Description

Control group: Placebo labeled as pill B is delivered by a non-interventionist in the study. It is used as 2 pills (completely identical to the intervention drug) every 6 hours and vaginally. According to the study protocol, an obstetrician-gynecologist will prescribe the pill. Vaginal pills are given to primiparous patients from the onset of labor pains and it is recommended to use 2 pills every 6 hours and vaginally. If possible, do not move for at least 2 hours after using the pill. Also, to ensure the use of the pill, participants are given a daily registration form to record each time the pill is used.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's triage at Ali Ibn Abi Taleb Hospital in Zahedan.

Full name of responsible person

Setareh Jami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Ebrahim Kord

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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

Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Setareh Jami
Position
Resident
Latest degree
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Other areas of specialty/work
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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
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
Information about the main outcome
When the data will become available and for how long
Access period starts 6 months after results are published.
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
The use of data for research purposes will be permitted. A written request from the requesting person and a guarantee of confidentiality of the information are required.
From where data/document is obtainable
Email: setareh jami setarehjami9111@gmail.com
What processes are involved for a request to access data/document
Submitting a request - Reviewing the request and complying with scientific and ethical principles -

Validating the requester - Responding	**Comments**