Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Efficacy of Extra-amniotic Dexamethasone Infusion in Cervical Ripening for Labor Induction: A Randomized Controlled Trial

Protocol summary

Study aim
To determine the efficacy of extra-amniotic dexamethasone infusion in cervical ripening for labor induction

Design
Randomized controlled clinical trial with parallel groups, open-label, phase 3, on 60 term pregnant women (30 in the intervention group and 30 in the control group). A random number table was used for randomization.

Settings and conduct
Randomized controlled clinical trial at Shariati Hospital, Bandar Abbas, on 60 term pregnant women with Bishop score <5 candidate for labor induction. Participants are allocated via random number table to intervention (dexamethasone + normal saline) and control (normal saline) groups. In both groups, oxytocin induction starts 6 hours later. No blinding is performed.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Term pregnant women at 37 to 42 weeks of gestation Bishop score less than 5 Candidate for termination of pregnancy with obstetric indication Requiring labor induction Maternal age between 18 and 45 years Informed consent Exclusion Criteria: Uterine anomalies Placenta previa Vasa previa Active genital herpes History of preterm premature rupture of membranes History of classical uterine incision History of more than one cesarean section Any contraindication to vaginal labor induction No informed consent

Intervention groups
Intervention group: Extra-amniotic infusion of 20 mg dexamethasone with normal saline via intracervical catheter. Control group: Extra-amniotic infusion of normal saline (placebo) via intracervical catheter. In both groups, labor induction with oxytocin is initiated 6 hours after the intervention.

Main outcome variables
Bishop score after catheter removal; induction-to-delivery time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260607069692N1**
Registration date: **2026-09-28, 1405/07/06**
Registration timing: **prospective**

Last update: **2026-09-28, 1405/07/06**
Update count: **0**

Registration date
2026-09-28, 1405/07/06

Registrant information

Name
Ali Jandaghi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3422 3028

Email address
ali.jandaghi@hums.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-07, 1405/07/15

Expected recruitment end date
2027-03-21, 1406/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Efficacy of Extra-amniotic Dexamethasone Infusion in Cervical Ripening for Labor Induction: A Randomized Controlled Trial

Public title

The Effect of Dexamethasone Infusion on Cervical Ripening for Labor Induction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Term pregnant women at 37 to 42 weeks of gestation. Bishop score less than 5. Candidate for termination of pregnancy with obstetric indication. Requiring labor induction. Maternal age between 18 and 45 years. Providing informed consent to participate in the study.

Exclusion criteria:

Having uterine anomalies. Having placenta previa. Having active genital herpes. Having a history of classical uterine incision. Having a history of more than one cesarean section. Having any contraindication to vaginal labor induction. Not providing informed consent to participate in the study. Having vasa previa. Having a history of preterm premature rupture of membranes (PPROM).

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method: This study uses simple randomization. To perform randomization, a list of eligible patients is prepared based on the order of admission to the hospital. Then, for each patient, a number is drawn from a random number table. Based on whether the number is even or odd, the patient is assigned to either the intervention or control group. Even numbers are allocated to the intervention group (extra-amniotic dexamethasone infusion) and odd numbers to the control group (extra-amniotic normal saline infusion). This process continues until the sample size of 60 participants (30 per group) is reached. Unit of Randomization: The unit of randomization in this study is individual. Each patient is independently assigned to one of the two study groups. Stratification: Stratified randomization is not used in this study. Randomization Tool: The randomization tool used in this study is a random number table. This table contains randomly generated numbers with no specific pattern, used for random allocation of patients to the study groups. Generation of Random Sequence: To generate the random sequence, a random number table is prepared. Starting from a random point in the table and moving row-wise or column-wise, numbers are drawn sequentially. For each patient, one number is drawn, and based on whether it is even or odd, the patient's group is determined. This sequence continues until the desired sample size (60 participants) is reached. The random sequence is prepared before the start of the study by an individual independent of the principal investigator (e.g., the statistical advisor) to avoid any bias. Allocation Concealment: For allocation concealment, the prepared random sequence is placed in sealed, sequentially numbered opaque envelopes. Each envelope contains the allocated group for each patient. The envelopes are opened only at the time of patient enrollment, after obtaining informed consent and confirming eligibility, by an individual not involved in the allocation process. This method prevents selection bias and ensures that the researcher is not aware of the allocated group of each patient in advance.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Mother Blvd.و

City

Bandarabbas

Province

Hormozgan

Postal code

1979735816

Approval date

2025-05-18, 1404/02/28

Ethics committee reference number

IR.HUMS.REC.1404.058

Health conditions studied

1

Description of health condition studied

Gestational Diabetes Melitus

ICD-10 code

O24.4

ICD-10 code description

Gestational diabetes mellitus

2

Description of health condition studied
Preeclampsia
ICD-10 code
O14
ICD-10 code description
Pre-eclampsia

3

Description of health condition studied
Intrahepatic Cholestasis of Pregnancy
ICD-10 code
K71.0
ICD-10 code description
Toxic liver disease with cholestasis

Primary outcomes

1

Description
Bishop score after catheter removal
Timepoint
Immediately after catheter removal (6 hours after intervention)
Method of measurement
Vaginal examination and scoring based on the standard Bishop scoring system (range 0-13)

2

Description
Induction-to-delivery time (hours)
Timepoint
From initiation of oxytocin infusion to delivery of the newborn
Method of measurement
Recording the time of oxytocin infusion initiation and delivery time using a clock, and calculating the difference in hours

Secondary outcomes

1

Description
First-minute Apgar score
Timepoint
One minute after birth
Method of measurement
Newborn examination and scoring based on the standard Apgar scoring system (range 0-10)

2

Description
Fifth-minute Apgar score
Timepoint
Five minutes after birth
Method of measurement
Newborn examination and scoring based on the standard Apgar scoring system (range 0-10)

Intervention groups

1

Description
Intervention group: Extra-amniotic infusion of 20 mg dexamethasone (dexamethasone ampoule 8 mg/2 mL, Iranian manufacturer) combined with normal saline 0.9% via intracervical catheter. The solution is infused once. Six hours after the intervention, labor induction with oxytocin is initiated.
Category
Treatment - Drugs

2

Description
Control group: Extra-amniotic infusion of normal saline (placebo) via intracervical catheter. Normal saline 0.9% is infused once in a volume similar to the intervention group. Six hours after the intervention, labor induction with oxytocin is initiated.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bandarabbas Shariati Hospital
Full name of responsible person
Dr. F. Ghadirikhah
Street address
Mother Blvd.
City
Bandarabbas
Province
Hormozgan
Postal code
1997935816
Phone
+98 916 429 6833
Email
djandaqi@live.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr. Shahram Zare
Street address
Deputy of research and technology, campus of Hormozgan University of Medical Sciences, Imam Hossein boulevard, Bandar Abas, Iran

City
Bandarabbas
Province
Hormozgan
Postal code
7919692004
Phone
+98 76 3128 1680
Email
djandaqi@live.com
Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr. Fatemeh Ghadirikhah
Position
Gynecology Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Mother Blvd
City
Bandarabbas
Province
Hormozgan
Postal code
1997935816
Phone
+98 916 429 6833
Email
djandaqi@live.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr. Fatemeh Ghadirikhah
Position
Gynecology Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Mother Blvd.
City
Bandarabbas
Province
Hormozgan
Postal code
1997935816
Phone
+98 916 429 6833
Email
djandaqi@live.com

Person responsible for updating data

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr. Fatemeh Ghadirikhah
Position
Gynecology Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Mother Blvd
City
Bandarabbas
Province
Hormozgan
Postal code
1997935816
Phone
+98 916 429 6833
Email
djandaqi@live.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

Final Report of the Clinical Trial

When the data will become available and for how long

Upon completion of the report

To whom data/document is available

Students, researchers and those who are interested in the matter

Under which criteria data/document could be used

For future research and application for labor facilitation and cervix preparation

From where data/document is obtainable

Final report of research or the paper published in Gynecology Journals

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

Library of the corresponding university or internet search

Comments