Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Extra-amniotic dexamethasone infusion with extra-amniotic salin infusion in cervical ripening for labor induction

Protocol summary

Study aim
This clinical trial aims to Compare Extra-amniotic dexamethasone infusion with extra-amniotic salin infusion in cervical ripening for labor induction.

Design
Clinical trial with control and intervention group, double – blind, randomized block method (permutation - 4 segmented), phase 3, sample size of 60

Settings and conduct
Sampling takes place in Amiralmomenin hospital.

Participants/Inclusion and exclusion criteria
60 women with gestational age of 37-42 weeks and Bishop Score < 5 will be put into the study if they are submitted. All patients with uterine anomalies ، placenta previa or placental low lying، Vasapravia، vaginal bleeding in the second and third trimester of pregnancy، Active genital herpes، intra-uterine fetal death) IUFD) and history of uterine classic incision will be excluded from the study.

Intervention groups
Patients will be injected Dexamethasone or normal saline alternately by EASI catheter (In fact, Dexamethasone will be infused into uterine by the extra amniotic injection). The interval between the labor inductions to onset of active phase will be measured and recorded. Every hour after injection، they will be examined for exiting catheter. Bishop score will be determined again after exiting the catheter and both groups will receive oxytocin for induction of labor. The duration of active phases till the second stage of labor ، the first minute Apgar up to fifth minute Apgar will be measured and recorded after birth.

Main outcome variables
Cervical ripening؛ Neonatal Apgar

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190107042266N2**
Registration date: **2020-01-27, 1398/11/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-27, 1398/11/07**
Update count: **0**

Registration date
2020-01-27, 1398/11/07

Registrant information

Name
Samaneh Lavvaf

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-20, 1398/10/30

Expected recruitment end date
2021-01-19, 1399/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Extra-amniotic dexamethasone infusion with extra-amniotic salin infusion in cervical ripening for labor induction

Public title

Comparison of Extra-amniotic dexamethasone infusion with extra-amniotic salin infusion in cervical ripening for labor induction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age of 37-42 weeks Candidate for induction of labor Bishop score of less than 5

Exclusion criteria:

Uterine anomalies Placenta previa or placental low lying Authentic History of vaginal bleeding in the second and third trimester of pregnancy Active genital herpes Intrauterine fetal death (IUFD) History of uterine classic incision Vasa Previa

Age

From **15 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

They will randomly be divided into two groups. For randomization, four segmented randomized blocks (permutation) will be used. Will be have two treatment methods. In 4 segmented blocks, two participants will be devoted to intervention group and two participants will be devoted to control group. There will be six different modes for 4 segmented blocks (TTCC, TCTC, TCCT, CCTT, CTCT, CTTC). Designation list will be prepared based on the randomized numbers created by excel with the help of a consultant before initiating the work (between 0 and 1). Rrandomized numbers "0 to 0.16" from the mixture of “TTCC", randomized numbers "0.16 to 0.33" from the mixture of " TCTC", randomized numbers "0.33 to 0.5" from the mixture of “TCCT”, randomized numbers "0.5 to 0.66" from the mixture of "CCTT", randomized numbers "0.66 to 0.83” from the mixture of "CTCT” and randomized numbers “0.83 to 1" from the mixture of "CTTC" will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses will be completed. Another person at the hospital, who is not involved in the trial and not aware of random sequences, will be assigned the participants into two groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2019-09-16, 1398/06/25

Ethics committee reference number

IR.SEMUMS.REC.1398.136

Health conditions studied

1

Description of health condition studied

Pregnant wemen

ICD-10 code

Pregnant s

ICD-10 code description

Z33

Primary outcomes

1

Description

Cervical ripening

Timepoint

The measurement of cervix at the beginning of the study and before initiation of the intervention (until 6 hours after initiation of the study) till the creation of bishop score of five and higher

Method of measurement

Vaginal exam based on Bishop score

Secondary outcomes

1

Description

Neonatal Apgar

Timepoint

First and fifth minutes after birth

Method of measurement

Standard method

Intervention groups

1

Description
Intervention group: Foley catheter (size 26) will be inserted into the cervix. The Foley catheter balloon will be filled with 30 ml of sterile water. 20 mg of dexamethasone will be mixed with sterile water to bring the volume to 20 ml. then the Solution will be infused with normal saline sterile infusion (at a rate of 1 ml/min) into the extra amniotic. Every hour after injection، They are examined for exiting catheter. After exiting catheter ، Bishop score will be determined again and labor induction will be implemented with oxytocin.

Category
Treatment - Drugs

2

Description
Foley catheter (size 26) is inserted into the cervix. The Foley catheter balloon will be filled with 30 ml of sterile water. 20 ml of distilled infused water and then the normal saline sterile infusion will be infused into the exterior amniotic. Every hour after injection، they will be examined for exiting catheter. After exiting catheter ، Bishop score will be determined again and labor induction will be implemented with oxytocin.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin hospital

Full name of responsible person
Dr Shahrzad Aghaamoo

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Amiralmomenin hospital, Mostafa Khomeini Blvd

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Sponsors / Funding sources

1

Sponsor

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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
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Dr Shahrzad Aghaamoo

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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