

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A Comparative Study about Maternal and Neonatal Outcomes of Using Extra-Amniotic Saline Infusion and vaginal Misoprostol for Cervical Ripening and Labor Induction in Pregnant Women with Unfavorable Cervix

Protocol summary

Study aim

Comparison of the effects of vaginally administered Misoprostol with extra-amniotic saline infusion on induction to delivery interval, maternal and neonatal outcomes in order to achieve shorter and also safer method for labor induction

Design

Two arm parallel group randomised trial with 72 pregnant women in each group, randomized with computer-generated table of random numbers.

Settings and conduct

This study was conducted in the labor ward of Kamali Hospital, Karaj, Iran. There was no blinding in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with singleton pregnancy; Unfavorable cervix; cephalic presentation of the fetus; 28 weeks of gestational age or more. Non-inclusion criteria: Pregnant women with contra-indications for labor induction; non-reassuring fetal status

Intervention groups

Intervention group 1: Vaginal Misoprostol; In this group, 25 micrograms of Misoprostol was administered every 4 hours up to 5 doses. Intervention group 2: Extra-amniotic saline infusion; this group received intravenous Oxytocin along with a maximum 12-hour saline solution infusion through Foley catheters that were placed above the internal cervical os.

Main outcome variables

Time to delivery; Vaginal vs cesarean delivery; Maternal and neonatal outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201024049128N1**

Registration date: **2020-12-01, 1399/09/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-01, 1399/09/11**

Update count: **0**

Registration date

2020-12-01, 1399/09/11

Registrant information

Name

Bitra Badehnoosh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3222 2021

Email address

badehnoosh@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-10, 1399/08/20

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study about Maternal and Neonatal

Outcomes of Using Extra-Amniotic Saline Infusion and vaginal Misoprostol for Cervical Ripening and Labor Induction in Pregnant Women with Unfavorable Cervix

Public title

Comparison of the Effectiveness of Intravaginal Misoprostol with Extra-Amniotic Saline Infusion in Labor Induction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Singleton gestation Alive fetus Cephalic presentation
Intact membranes Unfavorable cervix (Bishop score ≤ 6)
Reassuring fetal heart rate Gestational age ≥ 28

Exclusion criteria:

Non-cephalic presentation Adequate uterine contractions (3 contractions Lasting for 30sec/10 min) Ruptured membranes Cephalopelvic disproportion Multiple pregnancy Polyhydramnios Estimated fetal weight ≥ 4000 g or ≤ 1800 g Placental abruption, Placenta previa Unexplained vaginal bleeding Prior lower segment cesarean section/Scarred uterus Non-reassuring fetal status Clinically detected vaginal infections (exp: genital herpes) or chorioamnionitis Latex or Prostaglandins allergy or any contraindications receiving Prostaglandins, including a history of asthma, glaucoma, or cardiovascular disease Intrauterine fetal death Renal or hepatic failure

Age

No age limit

Gender

Female

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Women who consented to participate were randomly selected to receive either Misoprostol or Extra-amniotic Saline Infusion. Group assignment was determined from a computer-generated table of random numbers. Some opaque envelopes were used for concealment.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Ethics committee unit; Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2020-10-10, 1399/07/19

Ethics committee reference number

IR.ABZUMS.REC.1399.185

Health conditions studied

1

Description of health condition studied

Unfavorable cervix

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The mean time interval from start of induction to delivery

Timepoint

Time of birth

Method of measurement

Clock

2

Description

Duration of latent phase

Timepoint

At the end of latent phase

Method of measurement

Clock

3

Description

Duration of active phase

Timepoint

At the end of active phase

Method of measurement

clock

4

Description

Rate of delivery within 12 hours

Timepoint

At the end of study

Method of measurement

Patient's file

5

Description

Rate of delivery within 24 hours

Timepoint

At the end of study

Method of measurement

Patient's file

Secondary outcomes

1

Description

Cesarean rate

Timepoint

At the end of study

Method of measurement

Patient's file

2

Description

Incidence of tachysystole

Timepoint

Continuously

Method of measurement

Cardiotocography

3

Description

Incidence of hypertonus

Timepoint

Continuously

Method of measurement

Cardiotocography

4

Description

Apgar score

Timepoint

1 minute and 5 minutes after birth

Method of measurement

Examination of the newborn

5

Description

Incidence of meconium passage

Timepoint

At birth

Method of measurement

Examination of the newborn

6

Description

Incidence of chorioamnionitis

Timepoint

Every 3 hours

Method of measurement

Physical examination

Intervention groups

1

Description

Intervention group: Vaginal Misoprostol. Misoprostol is a prostaglandin E1 analog known to stimulate uterine contractions. In this study 100-microgram tablets were used. In this intervention group, 25 micrograms of misoprostol (1/4 of 100-microgram tablet) was inserted intravaginally in the posterior fornix every 4 hours up to 5 doses. The maximal cervical ripening period until labor induced was 24 hours, regardless of the number of doses received. Intravenous oxytocin was given to the misoprostol group for the following reasons: (1) active labor did not occur after the maximum number of doses of misoprostol had been given, (2) spontaneous rupture of the membranes occurred without an adequate contraction pattern, or (3) dilation was arrested (no change in cervical dilation for >2 hours)

Category

Treatment - Drugs

2

Description

Intervention group: Extra-amniotic saline infusion. Saline is a type of isotonic solution and a mixture of salt and water. The concentration is 9 grams per litre (0.9% saline). In this group, women underwent a speculum examination. After preparation of the cervix with Betadine solution, an 18-gauge Foley catheter balloon was inserted to above the internal cervical os. The balloon was inflated to 30 milliliters with sterile normal saline solution, the Foley catheter was taped to the inner aspect of the subject's thigh without any traction. A normal saline solution infusion of 30 mL per hour through the central lumen of the Foley catheter was initiated concurrently with intravenous oxytocin. Oxytocin infusion was started at a rate of 1.0 milliunits per minutes and was increased in nine stepwise increments to a maximum of 22.0 milliunits per minutes at 30-minute intervals as needed to achieve an adequate contraction pattern. The Foley catheter was removed for the following reasons: (1) 12 hours had elapsed since the initial placement (2) spontaneous rupture of membranes occurred, (3) evidence of fetal distress was noted, (4) the catheter was expelled spontaneously, or (5) the patient could no longer tolerate the procedure.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali hospital

Full name of responsible person

Bita Badehnoosh

Street address

Kamali hospital; Kamali alley; Shohada square;
Shahid Beheshti street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Nourisepehr

Street address

Vice Chancellor for Research; No.20; Saffarian alley;
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Research@abzums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Bita Badehnoosh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Bita badehnoosh

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Person responsible for updating data

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Position

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available