

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison of vaginal misoprostol with Foley catheter for cervical ripening and labor induction

Protocol summary

Study aim

Comparison of mechanical and drug methods in preparing cervix

Design

In two parallel groups using Foley catheter and Prostaglandin

Settings and conduct

A randomized clinical trial is conducted on pregnant women referred to Besat Hospital in Sanandaj, who have an indication of the termination of pregnancy for any reason (due to delivery, post date pregnancy)

Participants/Inclusion and exclusion criteria

Women referring to the delivery block of Besat Hospital indicating the induction of labor. Inclusion criteria: Gestational age equal to or greater than 37 weeks; by ultrasonography of the first-trimester And last menstrual period, inappropriate cervix and Bishop score of 1 equal to or less than 4, single pregnancy, vortex display, intact chorionic membrane and satisfaction to participate in the research. Patients are also adjusting in gravid distribution. Patients with previous history of cesarean or previous surgery on the uterus, vaginal bleeding, or Placenta previa, or the possibility of early detachment of the placenta, regular uterine contractions and possible susceptibility to contraindications for use of prostaglandins, as well as Intrauterine growth restriction and severe preeclampsia, or problems in controlling fetal heart sounds, fetal distress, are excluded.

Intervention groups

Two groups which using prostaglandin and mechanical methods of Foley catheter

Main outcome variables

Tachysystole, umbilical cord prolapse, Meconium stain, Uterine atony, Neonate Apgar score, Bishob score, Labor speed, Induced safety, Induction failure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170326033142N2**

Registration date: **2018-07-28, 1397/05/06**

Registration timing: **retrospective**

Last update: **2018-07-28, 1397/05/06**

Update count: **0**

Registration date

2018-07-28, 1397/05/06

Registrant information

Name

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Name of organization / entity

Kurdistan university of medical science

Country

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Recruitment status

Recruitment complete

Funding source

UNIVERSITY OF MEDICAL SCIENCES KURDISTAN VICE
CHANCELLOR IN RESEARCH AFFAIR

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

2016-09-22, 1395/07/01

Actual recruitment end date

2017-10-22, 1396/07/30

Trial completion date

empty

Scientific title

Comparison of vaginal misoprostol with Foley catheter for cervical ripening and labor induction

Public title

Traction effect with folly catheter on cervices ripening compared to vaginal misoprostol

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women referring to the delivery block of Besat Hospital indicating the induction of labor. Gestational age equal to or greater than 37 weeks Satisfaction to participate in the research intact chorionic membrane Vortex presentation Single pregnancy Inappropriate cervix and Bishop score 1 equal to or less than 4

Exclusion criteria:

fetal distress Problems in controlling fetal heart sounds severe pre-eclampsia Intrauterine growth restriction Contraindications for the use of prostaglandins Regular uterine contractions Early placental detachment Placenta previa Vaginal bleeding Previous cesarean section or previous surgery on the uterus

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

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

KURDISTAN UNIVERSITY OF MEDICAL SCIENCES

Street address

Kurdistan University of Medical Sciences Vice Chancellor in Research Affair Pasdaran Ave.

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6617713446

Approval date

2016-09-19, 1395/06/29

Ethics committee reference number

IR.MUK.REC.1396/105

Health conditions studied

1

Description of health condition studied

Cervical ripening

ICD-10 code

O80

ICD-10 code description

Encounter for full-term uncomplicated delivery

Primary outcomes

1

Description

Dilation

Timepoint

Every 1 hour

Method of measurement

Vaginal examination

2

Description

Effacement

Timepoint

Every 1 hour

Method of measurement

Vaginal examination

3

Description

Delivery progress time

Timepoint

Every 1 hour

Method of measurement

Vaginal examination

Secondary outcomes

empty

Intervention groups

1

Description

In the first group (misoprostol group), misoprostol 25 µg (200µg Samisaz tablets divided by divaider) is placed in the posterior fornix of the vagina and will be repeated

every 6 hours to a maximum of 3 doses (total 75 µg). If the patient does not spontaneously enter the phase of labor (regular uterine contractions accompanied by progressive changes in the cervix), after 12 hours of induced labor, oxytocin will be used to terminate the pregnancy.

Category

Treatment - Drugs

2**Description**

In the second group (Foley catheter group), Foley catheter No. 16 in sterile conditions (washing the vagina with Betadine), through the cervix into the uterus and then the balloon is filled with 30 ml of distilled water to be placed behind the inner hole To put The other end of the catheter, to provide traction with normal saline 500ml bag and hang beside the bed. If after 6 hours, the patient does not spontaneously enter the phase of labor, induction of labor with oxytocin begins.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Be'sat Hospital, Sanandaj

Full name of responsible person

Dr. Sorayya Rashid Zadeh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name

پایان نامه دستیار تخصصی جراح زنان و زایمان

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

Yes

Title of funding source

Sanandaj 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**

Sanandaj University of Medical Sciences

Full name of responsible person

Dr. Sorayya Rashid Zadeh

Position

Obstetrics and Gynecology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is from the proposal, raw data and project reports

When the data will become available and for how long

Data is available from the legal system six months after publication for two years

To whom data/document is available

All persons will be able to access the Kurdistan University of Medical Sciences's request to the Kurdistan University of Medical Sciences.

Under which criteria data/document could be used

For legal issues and the need to use data in future studies

From where data/document is obtainable

Sorayya Rashidzadeh

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

After submitting a request to the Kurdistan Research and Technology Dept. of Science and Technology, a call for submission is given.

Comments