Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 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, umblical 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
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Name of organization / entity
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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.
City
Sanandaj
Province
Kurdistan
Postal code
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

Street address

Be'sat Educational Hospita, Keshavarz St. Vakil 4way, sanandaj, Kurdistan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr.Nasrin Soufi Zadeh

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person
Dr.Shoaleh Shahgheybi

Position
Profesor Associated, Obstetrics and Gynecologist

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Sanandaj University of Medical Sciences

Full name of responsible person
Behzad Khalafi

Position
Research Associate, Researcher Soldier, General Physician of Kurdistan University of Medical Scien

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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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