Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Investigating the effect of vaginal washing before Misoprostol insertion on ripening cervix before labor induction

Protocol summary

Study aim
Investigating the effect of vaginal washing before Misoprostol insertion on cervical ripening before labor induction
Design
Clinical trials with control group, with parallel groups, double blind, randomized
Settings and conduct
The subjects were pregnant women with single-pregnant women undergoing pregnancy termination are admitted to Al-Zahra Hospital in Rasht, Iran, which were selected according to inclusion criteria. After giving explanations to individuals, they are randomly divided into two groups. And will be unaware of the type of intervention.
Participants/Inclusion and exclusion criteria
Inclusion criteria include all pregnant women with singleton pregnancy and candidates for termination of pregnancy. Exclusion criteria include occurrence of any complications requiring cesarean section termination.
Intervention groups
The intervention group includes pregnant women who receive vaginal washing with normal saline prior to misoprostol loading. The control group includes pregnant women who will receive only misoprostol suppositories.
Main outcome variables
The interval between misoprostol insertion Until the delivery

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20080826001096N7**
Registration date: **2019-08-18, 1398/05/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-18, 1398/05/27**
Update count: **0**
Registration date
2019-08-18, 1398/05/27

Registrant information
Name
Seyede Hajar Sharami
Name of organization / entity
Guilan University of Medical Science
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-07-23, 1398/05/01
Expected recruitment end date
2021-07-23, 1400/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of vaginal washing before Misoprostol insertion on ripening cervix before labor induction

Public title
Investigating the effect of vaginal washing before Misoprostol insertion on ripening cervix before labor induction
Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

pregnant women ages 18 to 40 Having 38 to 40 week pregnancy Having singleton pregnancy Having normal fetal heart rate (FHR) Having cephalic presentation Not having a ban on normal vaginal delivery (cephalopelvic disproportion) Having no uterine contractions spontaneously and effectively (less than three contractions in 30 minutes) Having a Bishop score of less than 6 Estimation of fetal weight less than 4000 grams Candidates for termination of pregnancy (post-term pregnancy (42 weeks and more), oligohydramnios, decreased fetal movements, abdominal biophysical profile score, maternal diabetes mellitus, intrauterine growth retardation, and preeclampsia)

Exclusion criteria:

Having sensitivity to known prostaglandin (with questions like skin manifestations, hives and rash, dyspnea and coughing, chest pain and blurred vision after taking prostaglandin) Having vaginal bleeding Preterm rupture of membranes Having a history of previous cesarean section or scar on the uterus Having fetal anomaly Having doubts about Chorioamnionitis

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **164**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible individuals are assigned blocked randomization size of 4 in sealed envelopes.The patients will be divided into two groups: vaginal washing (A) and control group (without vaginal washing) (B). Random sequences will be generated by computer software. After generating the list, each individual will be assigned a dedicated code and will be identified with this code during the study. The registration and randomization sequence are done by a resident of obstetric and gynecology. None of the participating in the study will be aware of the randomization list . Registration and randomization sequence are done by a third party.

Blinding (investigator's opinion)

Single blinded

Blinding description

None of the participating in the study will be aware of the randomization list and also sealed envelopes that are numbered sequentially will be used for allocation concealment the randomization process. and envelope relating to each individual only after confirming the eligibility criteria for entry into study for him and the signature of the consent will be opened form by individual.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, Shahid Siadati St., Namjoo Ave., Rasht, Guilan, Iran

City

Rasht

Province

Guilan

Postal code

66949- 41446

Approval date

2019-06-15, 1398/03/25

Ethics committee reference number

IR.GUMS.REC.1398.107

Health conditions studied

1

Description of health condition studied

Labor induction

ICD-10 code

O61.8

ICD-10 code description

Other failed induction of labour

Primary outcomes

1

Description

success of labor induction

Timepoint

Post-partum

Method of measurement

Duration from induction to active phase of labor

Secondary outcomes

1

Description

The duration of vaginal Misoprostol to successful labor induction

Timepoint
During labor
Method of measurement
hour

2

Description
Vaginal PH
Timepoint
Before and after vaginal washing
Method of measurement
Nitrazine paper

3

Description
Duration from induction to end of first stage of labor
Timepoint
During labor until the end of the first stage of labor
Method of measurement
hour

4

Description
Duration from induction to active phase of labor
Timepoint
During labor until the active phase of labor
Method of measurement
hour

5

Description
Maternal complications (tachysystole, hyperstimulation, etc.)
Timepoint
During labor
Method of measurement
Patient complaint

6

Description
Neonatal complications include meconium excretion, Apgar score less than 7, admission to the NICU
Timepoint
During labor until after delivery
Method of measurement
Observations by doctor

Intervention groups

1

Description
Intervention group: : Vaginal washing with normal saline 0.9%(20 cc) is performed once before Misoprostol insertion (25 micrograms vaginal in the fornix posterior vaginal) with a syringe.
Category
Treatment - Drugs

2

Description
Control group: Without vaginal washing, only Misoprostol suppository will be inserted (25 micrograms vaginal into the fornix posterior vaginal) .
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-zahra hospital
Full name of responsible person
Farnoush Farzi
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Al-zahra Hospital, Namjoo Ave., Rasht, Guilan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research vice-chancellorship, Guilan University of Medical Sciences
Full name of responsible person
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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
Research vice-chancellorship, Guilan 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
Rasht University of Medical Sciences

Full name of responsible person
Zakieh Bakhshipour

Position
Resident of Obstetric and Gynecology

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Position
Professor

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Gynecology and Obstetrics

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Person responsible for updating data

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Full name of responsible person
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MS.c of Midwifery

Latest degree
Master

Other areas of specialty/work
Midwifery

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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
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
Yes - There is 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

Title and more details about the data/document
Total data can be shared after people are unidentifiable.

When the data will become available and for how long
From 2020 for two years

To whom data/document is available
All people interested in academic and scientific institutions

Under which criteria data/document could be used
Contract between the two sides

From where data/document is obtainable
Dr. seyedeh Hajar sharami 009813133369224 Rasht, Namju street, Al-Zahra hospital

What processes are involved for a request to access

data/document

After email or phone call with Dr. Sharemi and if possible face to face meeting and after contract to determination the scope of authorities, the data will be available to the applicant. ,

Comments