Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of frequency of Natural vaginal delivery after preparation of cervix with evening primrose, EASI mechanical method and misoprostol in 41 week pregnant women

Protocol summary

Study aim

Determining the frequency of normal delivery after using three groups of evening primrose, mechanical and misoprostol in 41-week pregnant women hospitalized in Fatemieh Hospital in 1401

Design

A clinical trial of three groups, with parallel groups, randomized by random block allocation method, phase 3 on 420 pregnant women of 41 weeks.

Settings and conduct

Informed consent will be obtained from patients. After entering the delivery room, the patients undergo a vaginal examination and Bishop's score is calculated and then they are included in one of the three groups randomly. In the evening primrose group, one 1000 mg evening primrose capsule from Dana Pharmaceutical Company is prescribed vaginally every hour. Evening primrose is used until the beginning of the active phase of labor (exam 3-4 cm). In the mechanical group, using the Extra amnionic saline infusion method, a cervical Foley catheter is inserted and 30 cc of normal saline is injected per hour, and after inserting the balloon, the balloon is allowed to come out for a maximum of 12 hours. Then, in the third group of patients, misoprostol suppository 25 are placed vaginally. Bishop's score is determined every two hours in all three groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primiparous women at 41 weeks are candidates for termination of pregnancy by natural delivery Exclusion Criteria: Patients with active labor phase Patients with spontaneous onset of pain Not having an emergency delivery indication

Intervention groups

The effect of three methods (evening flower, mechanical method and misoprostol) in the delivery process of primiparous pregnant mothers is investigated. Pregnant mothers are randomly divided into 3 groups.

Main outcome variables

Comparison of natural birth process, labor duration, side effects and condition of the baby in three groups of evening primrose, mechanical and misoprostol.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230522058253N1**
Registration date: **2023-06-16, 1402/03/26**
Registration timing: **prospective**

Last update: **2023-06-16, 1402/03/26**
Update count: **0**

Registration date

2023-06-16, 1402/03/26

Registrant information

Name

neda alimohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0808

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of frequency of Natural vaginal delivery after preparation of cervix with evening primrose, EASI mechanical method and misoprostol in 41 week pregnant women

Public title

A comparative study of the effect of evening primrose, EASI mechanical method and misoprostol in Natural Vaginal Delivery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Primiparous women at 41 weeks are candidates for termination of pregnancy by natural delivery method

Exclusion criteria:

Pregnant women with IUFD, SGA, IUGR Pregnant women with spotting and abnormal placenta

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **420**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be consulted upon entering the hospital and informed consent will be obtained from the patient. After entering the delivery room, they undergo a vaginal examination and Bishop's score is calculated, and then they are included in one of the three groups randomly. Randomization is done by writing the letters A, B and C on three sheets and putting them in a box, and one of these sheets is taken out by the researcher for each patient. After completion, again for the next three patients, sheets will be removed with this random method until we reach the desired sample size.

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 hamadan University of Medical Sciences

Street address

Fatemieh hospital, Pastaran Ave.

City

hamadan

Province

Hamadan

Postal code

6517789971

Approval date

2023-01-28, 1401/11/08

Ethics committee reference number

IR.UMSHA.REC.1401.942

Health conditions studied

1

Description of health condition studied

Comparison of frequency of Natural vaginal delivery after preparation of cervix with evening primrose, EASI mechanical method and misoprostol in 41 wee

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bishop's scoring system

Timepoint

Two hours after using misoprostol and the EASI mechanical method and evening primrose

Method of measurement

Bishop's scoring system to check cervix inducibility

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: in the evening primrose group, one 1000 mg evening primrose capsule from Dana Pharmaceutical Company is prescribed vaginally every hour. Evening primrose is used until the beginning of the active phase of labor (exam 3-4 cm).

Category

Treatment - Drugs

2

Description
Intervention group2: In the mechanical group, using the Extra amnionic saline infusion method, a Foley cervical catheter is inserted and 30 cc of normal saline is injected per hour, and after the balloon is inserted, the balloon is allowed to come out for a maximum of 12 hours.
Category
Treatment - Devices

3

Description
Intervention group3: Misoprostol suppository 25 micrograms is placed vaginally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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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
Hamedan 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
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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable