

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the effect of transactional catheter and Extra-Amniotic Normal Saline Infusion (EASI) on cervical readiness in primiparous mothers who are candidates for termination of pregnancy with Bishop score less than 4 4in Ayatollah Mosavi Hospital in Zanjan in 2021-2022

Protocol summary

Study aim

Comparison of the effect of traction catheter and normal amniotic extraction (EASI) on cervical preparation in primiparous mothers candidates for termination of pregnancy

Design

This single-blind randomized clinical trial with parallel groups will be performed on 52 pregnant women. Patients are randomly divided into two groups by block randomization. In patients in EASI group, cervical catheter will be used and in cervical traction catheter group, cervical catheter will be used.

Settings and conduct

This single-blind randomized clinical trial study with parallel groups will be performed on 52 women with a gestational age of 37 weeks and older in Zanjan academic hospital. In this study, data collectors, outcome assessors, and manuscript writers will be completely unaware of the drug prescribing protocol.

Participants/Inclusion and exclusion criteria

Inclusion criteria are gestational age equal to or greater than 37 weeks (based on LMP and first trimester ultrasound), single pregnancy. Patients with a history of previous cesarean section, placenta previa, premature rupture of membranes, and people with preeclampsia will be excluded from the study.

Intervention groups

In EASI patients, 15 cc of normal saline solution is first injected into the cervical catheter balloon and then this infusion is continued at a rate of one milliliter per minute into the extraamniotic space. In the cervical traction catheter group, in the lithotomy position, the cervical catheter No. 24 passes directly through the inner hole of the cervix and its balloon will be filled with 30 cc of sterile serum.

Main outcome variables

Duration of stages one, two and three of labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220403054399N1**

Registration date: **2022-04-24, 1401/02/04**

Registration timing: **prospective**

Last update: **2022-04-24, 1401/02/04**

Update count: **0**

Registration date

2022-04-24, 1401/02/04

Registrant information

Name

fatemeh daraie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-10, 1401/02/20

Expected recruitment end date

2023-01-10, 1401/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of transactional catheter and Extra-Amniotic Normal Saline Infusion (EASI) on cervical readiness in primiparous mothers who are candidates for termination of pregnancy with Bishop score less than 4 in Ayatollah Mosavi Hospital in Zanjan in 2021-2022

Public title

The effect of transactional catheter and Extra-Amniotic Normal Saline Infusion (EASI) on cervical readiness

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Single tone pregnancy Gestational age more than 37 weeks

Exclusion criteria:

Premature rupture of membranes (PROM) previous cesarean section (CS) Placenta Previa Preeclampsia

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 52

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the block randomization method. The size of all blocks is equal. Random allocation software is also used to generate a random sequence of blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, data collectors, outcome assessors, and manuscript writers will be completely unaware of the prescribing protocol.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Jomhori BLV. Azadi Squ. Zanjan

City

Zanjan

Province

Zanjan

Postal code

1435689752

Approval date

2022-02-21, 1400/12/02

Ethics committee reference number

IR.ZUMS.REC.1400.502

Health conditions studied**1****Description of health condition studied**

labor

ICD-10 code

O60.2

ICD-10 code description

Term delivery with preterm labor

Primary outcomes**1****Description**

duration of first stage of labor

Timepoint

Not applicable

Method of measurement

hour

Secondary outcomes**1****Description**

Duration of second stage of labor

Timepoint

Not applicable

Method of measurement

Hour

Intervention groups**1****Description**

Intervention group: In EASI patients, 15 cc of normal

saline solution is first injected into the cervical catheter balloon and then this infusion is continued at a rate of one milliliter per minute into the extraamniotic space.

Category

Treatment - Devices

2**Description**

Intervention group: In the cervical traction catheter group, in the lithotomy position, the cervical catheter No. 24 passes directly through the inner hole of the cervix and its balloon will be filled with 30 cc of sterile serum.

Category

Treatment - Devices

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

Ayatollah Mousavi Hospital in Zanjan

Full name of responsible person

Fatemeh Daraie

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

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

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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

Zanjan 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**

Zanjan University of Medical Sciences

Full name of responsible person

Fatemeh Daraie

Position

Non-faculty specialist physician

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**

Zanjan University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data including the main and secondary outcomes can be shared.

When the data will become available and for how long

Access period starts from 2023

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Raw data is not available to individuals and upon request, the results of the requested statistical analysis will be available to individuals.

From where data/document is obtainable

Contact the research expert of the Infertility Clinic of Zanjan University to receive the required documents or data.

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

To submit a request, it is enough to contact the mentioned expert and send a written and signed request to her.

Comments