

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of cervical Hyoscine on the length of the first and second stages of labor of nulliparous women referred to Niknafs maternity hospital in Rafsanjan: A clinical trial

Protocol summary

Study aim

The effect of cervical hyoscine on the first and second stages length of labor in primiparous women referring to Niknafs hospital

Design

Clinical trial, with control group, with parallel groups, one blind, by randomization method through computer software will be divided into experimental and control groups.

Settings and conduct

This one-blind clinical trial will perform in 2021 on 120 primiparous women referring to Niknafs hospital in Rafsanjan. After explaining the purpose and period of the study and obtaining informed consent from the samples, they will assign in the experimental and control groups. The control group give one milliliter of single-dose distilled water with cervicovaginal syringes. All people should have at least 4 cm of dilatation and regular uterine contractions when administering cervicovaginal medication, and their membranes should be intact. The contents of the syringes and vaginal examinations will be injected by one person.

Participants/Inclusion and exclusion criteria

eligibility criteria: primiparas, full-term pregnancy, alive singleton with cephaic presentation, intact membranes people with a history of maternal medical diseases including cardiovascular diseases, tachycardia as well as vaginal bleeding, temperature above 38 ° C, history of conization and cervical resection by loop electric method will be excluded from the study.

Intervention groups

The experimental group give one milliliter dose of Hyoscine (equivalent to 20 mg) and the control group give one milliliter distilled water with needleless syringes (the drug will be poured on the upper edge of the cervix).

Main outcome variables

The length of the first and second stages of labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181219042051N3**

Registration date: **2021-08-14, 1400/05/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-14, 1400/05/23**

Update count: **0**

Registration date

2021-08-14, 1400/05/23

Registrant information

Name

Zohreh Ghorashi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

zghorashi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cervical Hyoscine on the length of the first and second stages of labor of nulliparous women referred to Niknafs maternity hospital in Rafsanjan: A clinical trial

Public title

The effect of cervical Hyoscine on the length of the first and second stages of labor

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Nulliparous Term pregnancy Single pregnancy alive fetus Cephalic presentation Intact membranes

Exclusion criteria:

People with a history of maternal medical diseases, including cardiovascular disease Tachycardia Vaginal bleeding Temperatures above 38 ° C History of conization History of cervical resection by loop method

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

random assignment by computerized method. 60 words of intervention and 60 words of control are given to the computer to randomly arrange them. This way we have a list in which 60 intervention words and 60 control words are randomly mixed. Then, eligible samples assign in intervention or control groups following this arrangement.

Blinding (investigator's opinion)

Single blinded

Blinding description

parturient are not going to be aware of the agents that be used in their vagina.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

ethics committee of Rafsanjan university of medical sciences

Street address

school of nursing midwifery. parastar street. rafsanjan. Iran

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Approval date

2021-04-20, 1400/01/31

Ethics committee reference number

IR.RUMS.REC.1400.095

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

The length of second stages of labor of neonate

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

The length of the third stage of labor

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

Apgar score of one and five minute

ICD-10 code**ICD-10 code description****4****Description of health condition studied**

postpartum abnormal hemorrhage

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The length of the first stage of labor

Timepoint

once after delivery

Method of measurement

According to the contents of the patient file, the time interval between dilatation is 4 cm until complete dilatation

2

Description

Length of the second stage of labor

Timepoint

once after delivery

Method of measurement

According to the contents of the patient file, the interval between complete dilatation and complete departure of the fetus

Secondary outcomes

1

Description

The length of the third stage of labor

Timepoint

after placental delivery

Method of measurement

According to the contents of the patient file, the time interval between the complete departure of the fetus and the time of the departure of the placenta

2

Description

neonate Apgar score

Timepoint

first and fifth minute after delivery

Method of measurement

Apgar score in the first and fifth minutes after birth

3

Description

Postpartum hemorrhage

Timepoint

two hours postpartum

Method of measurement

Bleeding up to two hours after delivery and diagnosis based on the measures needed to manage postpartum hemorrhage and diagnose midwife

Intervention groups

1

Description

Intervention group: The test group is given a single dose of 1 ml hyoscine vial (equivalent to 20 mg) with needleless syringes cervicovaginally (the drug will be poured on the upper edge of the cervix). All people should have at least 4 cm of dilatation and regular uterine contractions when administering cervicovaginal medication, and their water bag should be healthy.

Category

Treatment - Other

2

Description

Control group: The control group is given 1 ml of single-

dose distilled water with needleless syringes of the cervix (the drug is poured on the upper edge of the cervix). When using cervical medicine, all people should have at least 4 cm of regular uterine dilation and contraction, and their bladder should be healthy.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rafsanjan Niknafs Maternity Hospital

Full name of responsible person

zohreh ghorashi

Street address

Niknafs Maternity Hospital- Shohada Street - Rafsanjan

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Rafsanjan

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7713665881

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Fax

+98 34 3425 8497

Email

niknafs@rums.ac.ir

Web page address

<http://www.rums.ac.ir/index.aspx?fkeyid=&siteid=41&pageid=1281>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

vice chancellor for research& technology

Street address

imam ali street. main office of Rafsanjan university of medical sciences

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vcrt@rums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rafsanjan 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**

Rafsanjan University of Medical Sciences

Full name of responsible person

zohreh ghorashi

Position

assistant professor. member of scientific board

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

more information is not available

Study Protocol

No - There is not 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

No - There is not 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