

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Investigating the effect of vagiline cream on the facilitation and outcomes of childbirth

Protocol summary

Study aim

Use of Vagiline cream to facilitate and accelerate the delivery of pregnant women

Design

A clinical trial with a control group, with parallel groups, randomized, phase 2 on 70 patients, without blinding. Block randomization with software was used for randomization.

Settings and conduct

Women who were admitted for the onset of labor pains in the pain room of Taleghani Hospital of Arak University of Medical Sciences and while receiving routine care for proper allocation in groups, their cervix was randomly examined by a midwife every one hour up to six stages per group. The intervention is softened with Vagiline cream. The b-shop score is measured by a sampler once before the intervention and every 2 hours up to 24 hours after the intervention. For the control group, routine interventions will be performed and the same score as the intervention group will be recorded.

Participants/Inclusion and exclusion criteria

A pregnant woman during the 40th week of pregnancy with the criteria of age between 18 and 35 years, singleton, gestational age of 40 weeks without the onset of labor pains, B-shop score below 4, without suffering from internal disorders and surgery during pregnancy, no history of high-risk pregnancy, absence of obvious pelvic stenosis (in internal examination), absence of previous cesarean section and absence of water sac rupture.

Intervention groups

Pregnant women in the intervention group will have their cervix softened by a midwife every one hour up to six stages with Vagiline cream and their cervix diameter will be checked, and the control group, without receiving any cream, will be examined every hour up to six stages of the diameter of their cervix.

Main outcome variables

Bishab score before and after admission, average Apgar score in the first minute and fifth minute of labor in

newborns

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200112046087N8**

Registration date: **2023-06-15, 1402/03/25**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-15, 1402/03/25**

Update count: **0**

Registration date

2023-06-15, 1402/03/25

Registrant information

Name

Hanieh Babaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

haniehbabaei92@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of vagiline cream on the facilitation and outcomes of childbirth

Public title

Investigating the effect of vagiline cream on facilitating childbirth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Singleton Gestational age 40 weeks without onset of labor pains Bishop score below 4

Exclusion criteria:

High risk pregnancy Obvious pelvic stenosis Previous caesarean section Rupture of water bag Internal and surgical disorders during pregnancy

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the block randomization method, and in this two-group clinical trial, we will have four blocks. For each person who enters the study, a code is obtained from the software, and it is determined which group it belongs to (intervention or control). The work tool is random allocation software, which, in addition to simple randomization, is capable of generating random sequences using the block method. In order to conceal, we use allocation concealment. This method is such that before the allocation of the individual, the allocated group is not known. In this way, we use non-transparent envelopes sealed with a random sequence. In this method, each of the random sequences created is recorded on a card, and the cards are placed in the envelopes in order. In order to maintain the random sequence, the outer surfaces of the envelopes are numbered in the same order. Finally, the lids of the envelopes are glued and placed in a box. Blocking and preparation of envelopes is done by a person not involved in data sampling and analysis; in this way, the person who collects, the person who analyzes, and the participant are informed of the type of intervention received and what group each person belongs to. He has no information.

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 Shahid beheshti University of Medical Sciences

Street address

Shahid Chamran Highway - Yemen St. - Shahid Abbas Aarabi St. (Parvaneh) - Next to Taleghani Hospital - Shahid Beheshti University of Medical Sciences and Health Services

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2021-11-28, 1400/09/07

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.612

Health conditions studied

1

Description of health condition studied

Facilitate childbirth

ICD-10 code

O80.0

ICD-10 code description

Spontaneous vertex delivery

Primary outcomes

1

Description

Apgar score

Timepoint

The first and fifth minutes

Method of measurement

Using Virginia Apgar's Apgar chart

2

Description

Duration of onset of labor pains

Timepoint

During childbirth

Method of measurement

Calculation of the time interval between the intervention and the onset of real pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: use of Vagiline cream formulated and standardized in the Medical Research and Terminology Center to soften the cervix by the size of a finger in order to facilitate and speed up the opening of the cervix in order to let the baby out every one hour up to six stages by the midwife, check the cervix every hour up to six stages (to check effacement, engagement, and dilatation), and fill in the table of measurements.

Category

Treatment - Drugs

2

Description

Control group: checking the cervix every one hour up to six stages by a midwife (to check effacement, engagement, and dilatation) and filling in the table of measurements without using any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak University of Medical Sciences, Taleghani Hospital

Full name of responsible person

Fateme Shabani

Street address

Arak University of Medical Sciences, Blue wing, Department of Midwifery, Prophet Azam Complex, Sardasht Square, Arak

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3502

Email

fatemeshabani46897@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti Faculty of Traditional Medicine

Full name of responsible person

Mojgan Tansaz

Street address

No. 8, Shams Alley, Vali-e Asr Ave, The Faculty of Traditional Medicine of Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Email

sitm@sbm.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti Faculty of Traditional Medicine

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

Shahid Beheshti School of Traditional Medicine

Full name of responsible person

Hanieh Babaei

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Traditional Medicine

Street address

Faculty of Traditional Medicine, Shahid Beheshti University of Medical Sciences, No. 8, Shams Alley, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Email

haniehbabaei92@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti School of Traditional Medicine

Full name of responsible person

Mojgan Tansaz

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Faculty of Traditional Medicine, Shahid Beheshti University of Medical Sciences, No. 8, Shams Alley, Valiasr Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Email

tansaz_mojgan@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hanieh Babaei

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Traditional medicine

Street address

Faculty of Traditional Medicine, Shahid Beheshti University of Medical Sciences, No. 8, Shams Alley, Valiasr Ave, Tehran, Iran

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Postal code

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Email

haniehbabaei92@gmail.com

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

The questionnaires used and the information related to the main outcome will be shared with the applicants.

When the data will become available and for how long

Start the access period at least one month after the results are published

To whom data/document is available

Researchers

Under which criteria data/document could be used

After the publication of the article extracted from the clinical trial, the said person will notify his / her request by email or contact.

From where data/document is obtainable

Dr. Mojgan Tansaz Email: tansaz_mojgan@yahoo.com
Phone: 02188773525

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

Sending a request to the main executor of the project, Dr. Mojgan Tansaz, and reviewing the request by her

Comments