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@sbmu.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
Reasercher

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
Reasercher

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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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