Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of Hyoscine and Acupressure on Hugo point (LI 4) on Length of delivery stages in nuliparous women: A randomized controlled clinical trial.

Protocol summary

Summary

The aim of this randomized controlled trial is comparison of the effects of Hyoscine and Acupressure on Hugo point (LI 4) on Length of delivery stages in nuliparous women. Materials and methods: for comparison of the effects of Hyoscine and Acupressure on Hugo point on Length of delivery stages, a randomized controlled clinical trial will be designed. It will be conducted on nulliparous eligible women who are referred to Sabalan Hospital in Ardabil for delivery. Sampling method will be available random sampling. Then, the samples will be placed randomly in two intervention and one control group (three groups including Hugo, Hyoscine and control). So each group has 54 participants (total sample size: 162). Randomization will be conducted using computer software (http://www.random.org) with the method of block randomization with the block of size 3 and 6. To hide the assignment the type of intervention on the paper, it will be numbered inside the bursting matte envelopes. Interventions: In the Hugo group, the Hugo spot will be pressed gently at 5 cm dilatation for 30 seconds, and gradually the pressure will be increased to become quite severe so that the patient will feel numbness and heaviness around the area. The scholar's finger will be held for 1 minute, after which the pressure will be reduced and ceased within 30 seconds. The pressure will be continued for 20 minutes and will be performed at the dilatation of 6, 8 and 10 cm. In the Hyoscine group, 20 mg of Hyoscine will be injected intramuscularly at the start of the delivery phase (dilation of 5 cm), and vaginal examination will be performed every 2 to 3 hours. In the control group routine care will be provided. The length of the stages of delivery will be measured by the researcher through vaginal examination and will be recorded in partograph form. Primary outcomes: Active phase length and second stage of labor length. Secondary Outcome: The length of the third stage of labor.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709293027N39**
Registration date: **2017-11-10, 1396/08/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-10, 1396/08/19

Registrant information

Name

Fahimeh Sehhatie Shafaie

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

sehhatief@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research of Tabriz University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of Hyoscine and Acupressure on Hugo point (LI 4) on Length of delivery stages in nuliparous women: A randomized controlled clinical trial.

Public title
Comparison of the effects of Hyoscine and Acupressure on Hugo point on length of delivery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: 18 to 35 years old, gestational age of 37 to 42 weeks (according to LMP or ultrasound in less than 12 weeks),nulliparous, singleton pregnancy, cephalic presentation, intact amniotic sac at examination, or passing Maximum 6 hours of rupture of the amniotic sac, spontaneous onset of uterine contraction, having low risk pregnancy (such as the absence of chronic disease like heart disease, hypertension, lung disease, diabetes, anemia, urinary tract infection, thyroid disease, and epilepsy; not having abortion, dead fetus, bleeding or any abnormality when referring to the hospital); absence of cephalopelvic disproportion (CPD) during vaginal examination; height over 145 cm; no lesion in hugo points; not presence of any disabilities that lead to communication problems for the mother (deafness, blindness, etc.).Exclusion Criteria: meconıum-rich amniotic fluid; Any need for emergent intervention in mothers and fetuses such as bleeding, Burst contractions, Labor accelerated, Fetal distress,Placenta Decolman.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **162**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Samples are compiled using computer software (http://www.random.org) by random blocking with the size of the triple and six blocks in three groups. To hide the assignment of the type of intervention on the paper, it will be numbered inside the bursting matte envelopes.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi street, Tabriz, and East Azerbaijan
City
Tabriz
Postal code
Approval date
2017-09-23, 1396/07/01
Ethics committee reference number
IR.TBZMED.REC.1396.288

Health conditions studied

1

Description of health condition studied
Delivery
ICD-10 code
O80.0
ICD-10 code description
Spontaneous vertex delivery

Primary outcomes

1

Description
lenght of active phase of labor
Timepoint
Every 2-3 hours, from the onset of the active phase of labor to its completion and the onset of the second stage of labor
Method of measurement
With vaginal exame and registration in the form of a partographer

2

Description
The length of the second stage of labor
Timepoint
Every 30 minutes once, from the onset of the second stage of childbirth to its completion
Method of measurement
Via vaginal examination and recording in the form of a partogragh

Secondary outcomes

1

Description
length of the third stage of labor
Timepoint
After completing the third stage of labor
Method of measurement
Observe and determine the time using the clock and record in the partograph

Intervention groups

1

Description
Acupuncture Hugo Point: At 5 cm dilatation, the Hugo point will be pressed gently for 30 seconds, and gradually the pressure will be added to become quite severe so that the patient feels numbed and heavy around the area. The scholar's finger will be held for 1 minute, and then the pressure will be reduced and released within 30 seconds. The pressure will continue for up to 20 minutes, and will be performed at the dilatation of 6, 8 and 10 cm.
Category
Prevention

2

Description
Injection of Hyoscine: At the onset of the delivery phase (dilation of 5 cm), 20 milligrams of Hyoscine will be injected muscularly and every 2 to 3 hours vaginal examination will be done. Primery outcomes that are active phase duration, se cond and third stage of delivery in a check list and a partialograph form will be recorded.
Category
Prevention

3

Description
Control group: The researcher will attend the maternity clinic and all routine lab measures that will be performed in the two intervention groups will be performed except acupressure and hyosteine injections in the control group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Sabalan Hospital in Ardabil
Full name of responsible person
Solmaz Babazadeh
Street address
Sabalan Hospital, Vahdat Square
City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad-Reza Rashidi
Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi street
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Fahimeh Sehhatie Shafaie
Position
Master of Sciences in Midwifery
Other areas of specialty/work
Street address
Faculty of Nursing and Midwifery, South Shariati Street
City
Tabriz
Postal code
Phone
+98 41134796770
Fax
Email
sehhatief@tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Fahimeh Sehhatie Shafaie

Position
MS on Midwifery

Other areas of specialty/work

Street address
Faculty of Nursing and Midwifery, South Shariati Street

City
Tabriz

Postal code

Phone
+98 41334796969

Fax

Email
sehhatief@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Fahimeh Sehhatie Shafaie

Position
Master of Sciences in Midwifery

Other areas of specialty/work

Street address
Nursing and Midwifery Faculty, South Shariati Street

City
Tabriz

Postal code

Phone
+98 41 3379 6770

Fax

Email
Sehhatief@tbzmed.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty