

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

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Name of organization / entity

Tabriz university of Medical Sciences

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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: meconium-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**

length 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 exam 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 partograph

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

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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

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Position

Master of Sciences in Midwifery

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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

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Fahimeh Sehhatie Shafaie