Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The effect of acupuncture in reducing the labor pain in mothers referred to Akbrabadi hospital in 2021, a randomized clinical trial.

Protocol summary

Study aim
Study of the effect of acupuncture in reducing the pain of natural childbirth in mothers.

Design
A clinical trial with a control group, with parallel groups, single blind, randomized, worked on 32 patients. Also, the random function of Excel software was used for randomization.

Settings and conduct
The study design is a single-blind randomized clinical trial intervention. Sampling of patients referred to Akbarabadi Obstetrics and Gynecology Center.

Participants/Inclusion and exclusion criteria
The Criteria for inclusion in this study are: The Single pregnant women, Normal BMI (19.8-26), Number of the deliveries less than or equal to 1, the Fluency in Persian to understand information, Term pregnancy (37 to 40 weeks) based on ultrasound under 20 weeks, Dilatation 5 cm, the Proper uterine contraction In terms of number, duration and intensity, lasting more than 30 seconds and less than ten minutes apart, regular heart beat, normal fetal presentation, the spontaneous onset of the labor, no obstetric problems and no disease. Exclusion criteria include patient disagreement with the design and provisions of the stillbirth consent form, the multiple incomplete pregnancies, abortion, neonates, and major congenital anomalies (including: life-threatening, need for major surgery, Chromosomal trisomies), the presence of maternal medical diseases (preeclampsia, thrombophilia, hypertension) and the presence of PPROM, HTN, oligohydraminosis, amniotic fluid disorder , cesarean section, use of fetal heart monitor due to fetal distress.

Intervention groups
The intervention group is performed acupuncture in real areas, including: SP6-Sp9 - St36-Li4 - Li3.

Main outcome variables
The Reduction of labor pains as well as duration of the delivery time was seen significantly in the intervention group.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220303054175N1**
Registration date: **2022-03-26, 1401/01/06**
Registration timing: **retrospective**

Last update: **2022-03-26, 1401/01/06**
Update count: **0**

Registration date
2022-03-26, 1401/01/06

Registrant information

Name
Mohammad Reza Hashtroudi

Name of organization / entity
Akbar Abadi Hospital

Country
Iran (Islamic Republic of)

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+98 21 5560 6034

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-31, 1399/08/10

Expected recruitment end date
2021-02-12, 1399/11/24

Actual recruitment start date
2021-01-10, 1399/10/21

Actual recruitment end date
2021-02-12, 1399/11/24

Trial completion date
2021-02-27, 1399/12/09

Scientific title
The effect of acupuncture in reducing the labor pain in mothers referred to Akbrabadi hospital in 2021, a randomized clinical trial.

Public title
The effect of acupuncture in reducing the labor pain in mothers referred to Akbrabadi hospital in 2021, a randomized clinical trial.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Śĺngleton Pregnant mothers,Normal BMI (19.8-26),Number of deliveries equal to or less 1,Fluency in Persian to understand information,Term pregnancy (37 to 40 weeks) based on ultrasound under 20 weeks,Dilatation 5 cm,Proper uterine contraction in terms of number,Duration and intensity lasting more than 30 seconds and less than ten minutes apart,Regular heart rate,Natural display of the fetus,Spontaneous onset of labor,Do not have any obstetric problems and do not have the disease.

Exclusion criteria:
Patient's disagreement with entering the plan and provisions of the stillbirth consent form,Multiple miscarriages, with abortions,Neonates and congenital anomalies of major (including: life-threatening, need for major surgery, chromosomal trisomies), presence of maternal medical diseases (preeclampsia, thrombophilia, hypertension) and presence of PRROM, HTN, oligohydramenosis, amniotic fluid disorder, Previous cesarean section and use of fetal heart monitor due to fetal distress.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **32**
Actual sample size reached: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects (intervention group and main group) are placed in one of the two intervention or control groups, through a table of random numbers and blocking.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, which is a randomized clinical trial (RCT) of single blind, all participants in both intervention and control groups were unaware of the allocation of study groups.

Placebo
Not used

Assignment
Parallel

Other design features
In this method we use acupuncture which is the safest and cheapest way to reduce pain. By examining the effect of adding three new points, which are ST36, Li3, and SP9, and in comparison with previous international research, which focuses more on two points, SP6 and Li4, and also using Electrical stimulation will be able to measure the reduction of labor pain.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of] IRAN University of Medical Sciences

Street address
Tehran Hemat Highway next to Milad Tower

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Tehran

Province
Tehran

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14496145351

Approval date
2021-01-02, 1399/10/13

Ethics committee reference number
IR.IUMS.FMD.REC.1399.612

Health conditions studied

1

Description of health condition studied
Reducing the labor pains in the normal vaginal delivery by the acupuncture

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Study and evaluation of the effects of the acupuncture in reducing the delivery pains by stimulating the real points in this study which is selected as follows: SP6 -Sp9 -St36 -Li3-Li4.

Timepoint
The measurement of reducing the pain at this stage will compare in the period of 15 minutes - 30 minutes - 45 minutes.

Method of measurement
The Visual Analogue Scale (VAS) measures pain intensity. The VAS consists of a 10cm line, with two end points representing 0 ('no pain') and 10 ('pain as bad as it could possibly be')

Secondary outcomes

1

Description
Study and evaluation of the effect of the acupuncture in reducing the delivery pains by stimulating the unreal points in this study which is selected as follows: : LU5, LU6, LU8, ST39
Timepoint
The measurement of reducing the pain at this stage will compare in the period of 15 minutes - 30 minutes - 45 minutes.
Method of measurement
The Visual Analogue Scale (VAS) measures pain intensity. The VAS consists of a 10cm line, with two end points representing 0 ('no pain') and 10 ('pain as bad as it could possibly be').

Intervention groups

1

Description
Intervention group: Intervention group with acupuncture will includes the real points which following : SP6 -Sp9 - St36 -Li3-Li4
Category
Treatment - Other

2

Description
Control group: In contrast with the intervention group,there is a simulated control group, which considered by observing the entry and exit criteria, whose members receive acupuncture in insensitive areas to finally compare their results with the intervention group.The main acupuncture points of this group includes : LU5, LU6, LU8, ST3
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbarabadi Hospital
Full name of responsible person
Maryam Rahimi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Mohammad Reza Hashtroudi
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Hashtroudi

Position

Medical Intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Position

Medical intern

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available