

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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, oligohydramnios, 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)

Phone

+98 21 5560 6034

Email address

dr.hashtroudi.md@gmail.com

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:**

Singleton 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 PRRM, 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 J IRAN University of Medical Sciences

Street address

Tehran Hemat Highway next to Milad Tower

City

Tehran

Province

Tehran

Postal code

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

Street address

Mowlavi St., Ferdows Gardens Station

City

Tehran

Province

Tehran

Postal code

1168743514

Phone

+98 21 5563 7048

Fax

+98 21 5560 8012

Email

rahimi.m@iums.ac.ir

Web page address

<https://crtai.iums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Ahmad Hormati

Street address

Iran University of Medical Sciences Shahid Hemmat Highway Tehran, IRAN

City

TEHRAN

Province

Tehran

Postal code

14496145351

Phone

+98 21 8670 2030

Fax

+98 21 8862 2692

Email

research-m @iums.ac.ir

Web page address

<https://iums.ac.ir>

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

Street address

Iran University of Medical Sciences, Shahid Hemmat
Highway, Tehran, 1449614535, IRAN

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86709

Email

dr.hashtroudi.md@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Rahimi

Position

Assistant Professor, Consultant

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Iran University of Medical Sciences, Shahid Hemmat
Highway, Tehran, 1449614535, IRAN

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86709

Fax

+98 21 5560 8012

Email

rahimi.m@iums.ac.ir

Web page address

<https://cрта.iums.ac.ir>

Person responsible for updating data

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

Alternative medicine-acupuncture

Street address

Iran University of Medical Sciences, Shahid Hemmat
Highway, Tehran, 1449614535, IRAN

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 5560 6034

Email

dr.hashtroudi.md@gmail.com

Web page address

<https://iums.ac.ir/>

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