

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

A randomized clinical trial on comparison of efficacy of LI-4 and SP-6 acupuncture points and Sham acupuncture on intensity and duration of labor pain in pregnant women

Protocol summary

Summary

In this randomized clinical trial the efficacy of LI-4 and SP-6 acupuncture points and Sham acupuncture was compared on the intensity and duration of labor pain in pregnant women. In this study, 63 pregnant women in active phase of labor were recruited (32 in intervention group and 31 in control group). This study was single-blinded, while the pregnant women were not aware of their groups (intervention group versus control group). Inclusion criteria: 1-Persian speaking women 2-maternal age 20 - 40 years old 3-nulliparity 4-singleton pregnancy 5-being healthy 6-37-42 weeks of gestational age 7-cephalic fetal presentation 8-mothers with normal healthy fetus 9-healthy mothers with no underlying diseases such as overt diabetes, gestational diabetes and preeclampsia Exclusion criteria: 1-mothers who received analgesics prior to conducting intervention 2-mothers who needs emergency cesarean section. In this study, LI-4 and SP-6 acupuncture points was conducted in intervention group. Also, Sham acupuncture was conducted on the same points in control group. The primary outcomes were considered as comparing the pain score before and after intervention and duration of labor.

General information

Acronym

Preterm delivery

IRCT registration information

IRCT registration number: **IRCT2013061310657N2**

Registration date: **2015-07-26, 1394/05/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-26, 1394/05/04

Registrant information

Name

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science

Expected recruitment start date

2011-10-01, 1390/07/09

Expected recruitment end date

2012-09-30, 1391/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized clinical trial on comparison of efficacy of LI-4 and SP-6 acupuncture points and Sham acupuncture on intensity and duration of labor pain in pregnant women

Public title

Efficacy of conducting acupuncture on intensity and duration of labor pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Persian speaking women 2-maternal age 20 - 40 years old 3-nulliparity 4-singleton pregnancy 5-being healthy 6-37-42 weeks of gestational age 7-cephalic fetal presentation 8-mothers with normal healthy fetus 9-healthy mother with no underlying diseases such as overt diabetes, gestational diabetes and preeclampsia Exclusion criteria: 1-mothers who received analgesics prior to conducting intervention 2-mothers who needs emergency cesarean section

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Zand Avenue

City

Shiraz

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

CT-P-91-4395

Health conditions studied

1

Description of health condition studied

labour pain

ICD-10 code

O30-O48

ICD-10 code description

Maternal care related to the fetus and amniotic cavity and possible delivery problems

Primary outcomes

1

Description

duration of labour

Timepoint

Immediately after intervention

Method of measurement

Questionnaire

2

Description

Severity of pain

Timepoint

Before and immediately after the intervention

Method of measurement

Visual analogue pain scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention1: The acupuncture was conducted in intervention group after initiation of the active phase of labor defined by cervical dilatation of at least 4 centimeters and uterine contractions at least 3, each lasting for more than 40 seconds within 10 minutes. Intervention was done for 20 minutes in LI-4 and SP-6 points using C-type acupuncture needles (Seirin GMBH, Neu-lsenburg, Germany). SP-6 point is located four finger width above the medial malleolus on the posterior border of the tibia. LI-4 point is located on the dorsum of the hand, between the 1st and 2nd metacarpal bones, in the middle of the 2nd metacarpal bone on the radial side. Intervention was performed until patient reported sensation of tingling, numbness or warmth, and then rotated clock-wise every 5 minutes.

Category

Treatment - Other

2

Description

Intervention 2: In the control group, sham acupuncture was performed by superficial contact of needles in the mentioned points (LI4 and Sp6).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

Zand Avenue

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

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City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

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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