Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of LI4 and LI11 Electro- acupressure on low back and pelvic pain in pregnant women

Protocol summary

Study aim

• Determination of electrical stimulation effect of LI4 and LI11 pressure points on lumbar and pelvic pain in pregnant women

Design

The present study was designed as a randomized double-blind clinical trial (intervention and control).

Settings and conduct

In this study, pregnant women referred to health centers in Bojin Zahra city who are eligible for inclusion in the study will be available after obtaining informed consent and obtaining written consent.Then, by filling out a demographic checklist, pregnancy, and completing the Roland Morris LBP and visual analogue questionnaire, people with a score above 12 in the Roland Morris LBP questionnaire and an equal score of more than 4 in the visual analogue will be included. Samples were randomly divided into control and intervention groups using randomized blocking method.In the intervention group, in addition to receiving routine prenatal care for 4 weeks, they receive acupressure twice a week through a two-channel tensile device at LI11, LI4 pressure points for 15 minutes, and information was obtained immediately by Roland Morris questionnaire and visual analogue questionnaire. After the intervention, each session in Venice will be reviewed and followed up at 2, 4, and 6 weeks after the intervention.

Participants/Inclusion and exclusion criteria

Having lumbopelvic pain Ages 18 to 35 years Gestational age 26-32 weeks Gravida 1 and singleton pregnancy

Intervention groups

The control group will receive standard prenatal care, and for the intervention group, in addition to standard prenatal care, twice a week for 4 minutes each and for 15 minutes will be electrically stimulated by a two-channel tensile device at Li4 and Li11 pressure points. Will find out.

Main outcome variables

Acupuncture, Hip and Back Pain, Pregnancy Age, Mother's Occupation, Age, Education, Pregnancy Age

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191209045673N1**
Registration date: **2020-01-29, 1398/11/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-29, 1398/11/09**
Update count: **0**

Registration date

2020-01-29, 1398/11/09

Registrant information

Name

Parvaneh Alirezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 28 3441 2386

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2020-06-18, 1399/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of LI4 and LI11 Electro- acupressure on low back and pelvic pain in pregnant women

Public title
Effect of LI4 and LI11 Electro- acupressure on low back and pelvic pain in pregnant women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women with lumbopelvic pain Gestational age 26 to 32 weeks Gravida 1 singleton Ages 18 to 35 years

Exclusion criteria:
Having mental disorders. Having skeletal muscle disorders. Use of psychotropic drugs. Using other pain relief techniques such as exercise in water, yoga and ... Skin lesions at acupuncture points.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
In the first step, the eligible samples will be selected who are willing to participate in the study, and then they will be divided into two groups (intervention and control) using block randomization.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences

Street address
Shahid Beheshti, Ave, Mavedat, St

City
Qazvin

Province
Qazvin

Postal code
3415613911

Approval date
2019-12-07, 1398/09/16

Ethics committee reference number
IR.QUMS.REC.1398.213

Health conditions studied

1

Description of health condition studied
lumbopelvic pain

ICD-10 code
M 54.5

ICD-10 code description
Low Back pain

Primary outcomes

1

Description
lumbopelvic pain

Timepoint
Measurements of lumbopelvic pain before intervention and immediately after the intervention in each visit and followed up at 2, 4 and 6 weeks after the intervention.

Method of measurement
Using Roland Morris Low Back Pain Inventory and Visual Analogue Scal

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study there is an intervention group, for the intervention group in addition to standard prenatal care, twice a week for 4 weeks and each time for 15 minutes electrical stimulation by two-channel tensile device at pressure points Li4 and Li11 at They will find.

Category
Treatment - Other

2

Description
Control group: Standard Prenatal Care

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Health Centers in the city of Bouin Zahra

Full name of responsible person
Fatemeh Ranjkesh

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School of Nursing and Midwifery, Qazvin University of Medical Sciences, Bahonar Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Vice chancellor for research, Qazvin University of Medical Sciences

Street address
Vice Chancellor for Research and Technology, Qazvin University of Medical Sciences, Shahid Beheshti Blvd.

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Grant name

Grant code / Reference number

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

Title of funding source
Qazvin University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Fatemeh Ranjkesh

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
School of Nursing and Midwifery, Qazvin University of Medical Sciences, Bahonar Ave. Midwifery Translations of midwifery NounFrequency مامایی midwifery قابلگی midwifery, midwife Examples of Midwifery midwifery services Synonyms of midwifery Noun tocology obstetrics ob

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
All data contains code and is identifiable.

When the data will become available and for how long
1399

To whom data/document is available
Qazvin University of Medical Sciences

Under which criteria data/document could be used
If approved by Qazvin University of Medical Sciences

From where data/document is obtainable
Qazvin University of Medical Sciences

What processes are involved for a request to access data/document
Visit Qazvin University of Medical Sciences and submit a written application or request an email to F.ranjkesh@qums.ac.ir

Comments