

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing traditional medicine product with placebo on low back and posterior pelvic pain in pregnant women : Randomized Clinical Trial Study

Protocol summary

Summary

this study is randomized controlled clinical trial triple blind .The purpose of this study is Evaluation of the impact of traditional medicine product in the treatment of low back pain in pregnancy This clinical trial will be performed at Tehran University of Medical Sciences, in 2014.80 pregnant women with non-specific chronic low back pain will be selected through simple non-probability sampling .The patients were randomly divided into two groups of 40 subjects. One group received the traditional medicine product and the other group received the placebo . The outcome were assessed with Roland-Mores disability questionnaire and visual analogue scale (VAS)at before, 1 week and 2 week after interventions . Primary outcome of this study is improvement in back pain during pregnancy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091419150N1**

Registration date: **2015-01-01, 1393/10/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-01, 1393/10/11

Registrant information

Name

Safieh Mohebitabar

Name of organization / entity

Tehran University of Medical Sciences(TUMS)

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Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tehran University of Medical Sciences(TUMS)

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing traditional medicine product with placebo on low back and posterior pelvic pain in pregnant women : Randomized Clinical Trial Study

Public title

Evaluation the effect of traditional medicine product on low back and posterior pelvic pain in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18- 35 y; gestational age 12 - 32week; having pain score $\geq$ 2 (by visual analog scale(VAS) Exclusion criteria: patient's dissatisfaction; taking any analgesics; history of spinal surgery, spine and pelvic trauma; pregnancy urges

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: 80

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences(TUMS)

Street address

Tehran University of Medical Sciences ,Ghods st ,tehran

City

Tehran

Postal code

1417614411

Approval date

2014-11-23, 1393/09/02

Ethics committee reference number

8821309005-128051

Health conditions studied**1****Description of health condition studied**

low back pain in pergnancy

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes**1****Description**

Reduce low back pain

Timepoint

1 week after intervention

Method of measurement

VAS

Secondary outcomes**1****Description**

Quality of life

Timepoint

1 and2 weeks after interventions

Method of measurement

Roland-Mores disability questionnaire

Intervention groups**1****Description**

intervention group : 7 drops of topical traditional medicine product oil for 10 cm2 on skin of painful part two times daily for 14 days

Category

Treatment - Drugs

2**Description**

control group: 7 drops of topical placebo oil for 10 cm2 on skin of painful part two times daily for 14 days

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Maternal, Fetal, and Neonatal Research Center, Tehran University of Medical Sciences(TUMS)

Full name of responsible person

Safieh Mohebitabar

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Moheb e yas hospital, North Ostad Nejatollahi, Karimkhan st

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Tehran University of Medical Sciences(TUMS)

Full name of responsible person

Mahdi Jahromi

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Traditional Medicine and Pharmacy Research Center, Jamali Str, Vafamanesh Str, Tehran

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Tehran

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 of Tehran University of Medical Sciences(TUMS)

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
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Full name of responsible person
Safieh Mohebitabar

Position
Traditional MedicinePhd candidate

Other areas of specialty/work

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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