

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of core stabilization exercises focusing on pelvic floor and deep abdominal muscles on pain, functional disability and quality of life in pregnant women with lumbopelvic pain

Protocol summary

Study aim

An appropriate guide to relieving lumbopelvic pain in pregnant women in a specific, targeted and conservative manner.

Design

Clinical trial with community-based and pragmatic control group, with parallel, double-blind, randomized groups

Settings and conduct

This study is done for 10 weeks and 3 sessions a week in the training group. Each group therapy session lasted 60 minutes, including 10 minutes of general warm-up, 40 minutes of stability exercises, focusing on the deep abdominal and pelvic floor muscles, and 10 minutes of cooling exercises.

Participants/Inclusion and exclusion criteria

Entry Requirements: 18 years and older First pregnancy
Week 14-18 of pregnancy Lumbopelvic pain for more than one week
Exit Requirements: Abortion history High-risk pregnancy Medicinal Therapies during pregnancy
Lumbopelvic pain history before pregnancy Contra indication of exercise during pregnancy to diagnose of doctor

Intervention groups

In the training group, stability exercises on deep abdominal muscles and pelvic floor muscles in 3 stages is done by isometric contraction, isolation contraction and co-contraction, then loading low load into them and eventually combining with functional postures. The control group only received usual care and education from a doctor or midwife, but they are not prohibited from exercising themselves.

Main outcome variables

Intensity of pain, functional ability, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181007041265N1**

Registration date: **2018-10-24, 1397/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-24, 1397/08/02**

Update count: **0**

Registration date

2018-10-24, 1397/08/02

Registrant information

Name

Hosein Negahban

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 7029

Email address

negahbanh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of core stabilization exercises focusing on pelvic floor and deep abdominal muscles on pain, functional disability and quality of life in pregnant women with lumbopelvic pain

Public title

Stabilization exercises in improvement of lumbopelvic pain in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 years and older First pregnancy Week 14-18 of pregnancy Lumbopelvic pain more than 1 week

Exclusion criteria:

Abortion history High-risk pregnancy Medicinal Therapies during pregnancy Lumbopelvic pain history before pregnancy Contra indication of exercise during pregnancy to diagnose of doctor

Age

From 18 years old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization Sealed envelopes

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will be unaware of the existence of the two groups and which group they are in. An individual has the responsibility to evaluate patients in three stages as well as which group of patients will be unaware of.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Vakilabad

City

Mashhad

Province

Razavi Khorasan

Postal code

9185763788

Approval date

2018-10-07, 1397/07/15

Ethics committee reference number

IR.MUMS.REC.1397.163

Health conditions studied

1

Description of health condition studied

Lumbopelvic pains

ICD-10 code

026

ICD-10 code description

Maternal care for other conditions predominantly related to pregnancy

Primary outcomes

1

Description

Intensity of pain

Timepoint

Before the start of the treatment, immediately after the completion of the program, the last week of pregnancy and 6 weeks after delivery

Method of measurement

Visual Analogue Scale

2

Description

Functional disability

Timepoint

Before the start of the treatment, immediately after the completion of the program, the last week of pregnancy and 6 weeks after delivery

Method of measurement

Oswestry disability index questionnaire

3

Description

Quality of Life

Timepoint

Before the start of the treatment, immediately after the completion of the program, the last week of pregnancy and 6 weeks after delivery

Method of measurement

The World Health Organization Quality of Life Questionnaire (WHOQOL-BREF)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This study was conducted for 10 weeks and 3 sessions per week in the training group, one session grouped under the supervision of a physiotherapist. Since it's difficult to attend training sessions at all sessions, doing 2 sessions of weekly exercises is done by giving a visual instruction to a person at home. Each group therapy session lasted for 60 minutes, including 10 minutes of general warm-up (walking), 40 minutes of stability training, focusing on abdominal muscles and pelvic floor, and 10 minutes of cooling training (including breathing and relaxation exercises). The exercises at home are similar to the same group exercises and are performed at least twice a week for 30 minutes. In the training group, the exercise is performed in three stages, such that the first phase consists of four sessions, which in 2 sessions First, on the isometric contraction and the isolation of the abdominal muscles and pelvic floor muscles in various positions, such as four hands and feet, supine, sitting and standing, and in the next 2 sessions, exercises were made by concurrent abdominal muscles and pelvic floor muscles in the position The above mentioned is done. The second stage, if properly performed, will begin muscle contraction, so that 3 sessions, while maintaining abdominal contraction and pelvic floor, will be loaded quantitatively by the controlled movements of the limbs in different positions. In the third phase, during 3 sessions, this is also a contraction of the muscles, with functional postures and activities that have already exacerbated the symptoms of the patient. At this stage, the patient is encouraged to activate these muscles regularly during daily activities. It should be noted that during each treatment session, each of the exercises will be performed in 10set 10 second

Category

Treatment - Other

2

Description

Control group: The control group received only the usual care and education from the doctor or midwife, but they are not prohibited from exercising themselves.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mobini hospital

Full name of responsible person

Samira Farazmehr

Street address

Mobini hospital, Kashefi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Vakilabad

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Tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hosein Negahban

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Hosein Negahban

Position

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Latest degree

Ph.D.

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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