

# 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

#### City

Sabzevar

#### Province

Razavi Khorasan

#### Postal code

9613984191

#### Phone

+98 51 4423 8100

#### Email

mobini.h@medsab.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

Vakilabad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9185763788

##### Phone

+98 51 3882 7029

##### Email

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

**Street address**

Vakilabad

**City**

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**Province**

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**Postal code**

9185763788

**Phone**

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**Email**

negahbanh@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Hosein Negahban

**Position**

professor

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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

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Professor

**Latest degree**

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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