

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jun 2026

### The effect of pelvic floor muscle exercises on pelvic girdle pain and quality of life in pregnant women

#### Protocol summary

##### Study aim

Determining the effect of pelvic floor muscle exercises on pelvic girdle pain and quality of life in pregnant women

##### Design

A clinical trial with a control group, with parallel, randomized groups, is performed on 60 patients. The samples are divided into two random groups in the form of quadruple random blocks A, A, B, B.

##### Settings and conduct

This study is performed in Taleghani Hospital in Arak. Samples will be selected from pregnant women with pelvic lumbar pain. Samples are randomly divided into two groups of intervention and control.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women in the second and third trimesters of pregnancy, confirmation of pelvic girdle pain with clinical test, moderate to severe pelvic girdle pain, age between 20 to 35 years, pain in one or more pelvic joints. Exclusion criteria: Previous history of significant lumbar or pelvic injury, use of steroids or analgesics, acute and chronic underlying disease.

##### Intervention groups

Group 1 (intervention): The patient should do pelvic floor muscle exercises 2 times a day and 20 times each time. Continue this exercise for 4 weeks. Exercises are performed in such a way that each time the patient contracts his pelvic floor muscles for 5-10 seconds and relaxes for 5-10 seconds according to his ability. .Group 2 (control): No special action is taken.

##### Main outcome variables

Pelvic girdle pain and quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130731014229N13**

Registration date: **2022-04-26, 1401/02/06**

Registration timing: **prospective**

Last update: **2022-04-26, 1401/02/06**

Update count: **0**

##### Registration date

2022-04-26, 1401/02/06

##### Registrant information

###### Name

Hadi Jafari manesh

###### Name of organization / entity

Arak University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3417 3503

###### Email address

jafarimanesh@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-21, 1401/02/31

##### Expected recruitment end date

2022-12-21, 1401/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of pelvic floor muscle exercises on pelvic girdle pain and quality of life in pregnant women

##### Public title

The effect of pelvic floor muscle exercises on pelvic

girdle pain and quality of life

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Pregnant women in the second and third trimesters of pregnancy Confirmation of pelvic girdle pain with clinical test Moderate to severe pelvic girdle pain Age between 20 to 35 years Pain in one or more pelvic joints

### Exclusion criteria:

Previous history of significant lumbar or pelvic injury Use of steroids or analgesics Acute and chronic underlying disease

## Age

From **20 years** old to **35 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The samples are randomly assigned to quadruple blocks A, A, B, B in random groups. So that 16 blocks of 4 letters A and B are made up. Then a block is randomly selected. RAS random allocation software will be used to randomly select blocks. A indicates sample placement in intervention group and B indicates sample placement in control group. First, a block will be randomly identified by RAS software and then the first eligible sample will be entered into the intervention or control group according to the order of the letters A or B. Sampling will continue until all samples are selected.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Factorial

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

##### Street address

Basij Sq.

##### City

Arak

## Province

Markazi

## Postal code

3819693345

## Approval date

2021-07-11, 1400/04/20

## Ethics committee reference number

IR.ARAKMU.REC.1400.084

## Health conditions studied

### 1

#### Description of health condition studied

Pelvic girdle pain

#### ICD-10 code

Z34

#### ICD-10 code description

Encounter for supervision of normal pregnancy

## Primary outcomes

### 1

#### Description

Pelvic girdle pain

#### Timepoint

Before the intervention and four weeks after the intervention

#### Method of measurement

Pelvic Belt Pain Questionnaire

### 2

#### Description

Quality of Life

#### Timepoint

Before the intervention and four weeks after the intervention

#### Method of measurement

Short form of quality of life questionnaire (sf-36)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The patient should do pelvic floor muscle exercises 2 times a day and 20 times each time. Continue this exercise for 4 weeks. Exercises are performed in such a way that each time the patient contracts his pelvic floor muscles for 5-10 seconds and relaxes for 5-10 seconds according to his ability.

#### Category

Treatment - Other

2

**Description**

Control group: There is no specific procedure

**Category**

N/A

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Taleghani Hospital

**Full name of responsible person**

Hadi Jafarimanesh

**Street address**

Emamkhomeini Blvd

**City**

Arak

**Province**

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**Postal code**

3816149369

**Phone**

+98 86 3277 6063

**Email**

nurse\_science@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Alireza Kamali

**Street address**

Basij Sq. Arak

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3848176341

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+98 86 3417 3536

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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**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Hadi Jafarimanesh

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

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## Person responsible for updating data

### Contact

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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