

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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

Markazi

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

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3536

Email

nurse_science@yahoo.com

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

Basij Sq. Arak

City

Arak

Province

Markazi

Postal code

6941738481

Phone

+98 86 3417 3503

Email

nurse_science@yahoo.com

Person responsible for scientific 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

Basij Sq. Arak

City

Arak

Province

Markazi

Postal code

6941738481

Phone

+98 86 3417 3503

Email

nurse_science@yahoo.com

Person responsible for updating data

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

Basij Sq. Arak

City

Arak

Province

Markazi

Postal code

6941738481

Phone

+98 86 3417 3503

Email

nurse_science@yahoo.com

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