Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of the pelvic belt on muscle activity of the pelvis muscles in pregnant women with pregnancy-related pelvic pain: A parallel-groups clinical study

Protocol summary

Study aim

The aim is to evaluate the effect of the pelvic belt on pelvic muscle activity in pregnant women with pelvic pain.

Design

A clinical trial with the intervention group, control group and a group including healthy pregnant women, with parallel, randomized, phase 1 groups on 51 patients. The locking method was used for random assignment of study groups.

Settings and conduct

Assessments are performed in the Faculty of Rehabilitation, Isfahan University of Medical Sciences in the spring of 1401. Three groups of pregnant women participate in this study. These assessments include electromyographic examination through superficial electrodes in the distal and proximal pelvic muscles, visual analog scale evaluation and, the Pain Catastrophizing Questionnaire and the Pelvic Pain Questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Pregnant women with pelvic pain, age 25 to 35 years, in the first pregnancy. 2. The onset of pelvic pain from 18 weeks onwards. 3. Positive result of two tests from the mentioned tests (posterior pelvic pain stimulation test, Patrick Fabers test, Trendelenburg modified test and, active straight leg raising test). 4. According to VAS assessment, the amount of pelvic pain is more than 3. Exclusion criteria: 1. Pelvic pain and low back pain before pregnancy. 2. Red flags symptoms. 3. Multiple pregnancies. 4. Pregnancy with systemic diseases.

Intervention groups

17 pregnant women with pelvic pain who receive a pelvic belt. 17 pregnant women with pelvic pain who receive manuals. 17 healthy pregnant women who do not receive any intervention.

Main outcome variables

Root Mean Square (RMS), Median Frequency (Med . F), Mean Frequency (Mean . F), Visual Analogue Scale (VAS), Pain Catastrophizing Scale (PCS) and Pelvic Girdle Questionnaire (PGQ).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220330054372N1**
Registration date: **2022-05-08, 1401/02/18**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-08, 1401/02/18**
Update count: **0**

Registration date

2022-05-08, 1401/02/18

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of the pelvic belt on muscle activity of the pelvis muscles in pregnant women with pregnancy-related pelvic pain: A parallel-groups clinical study

Public title
The effect of the pelvic belt on muscle activity of the pelvis muscles in pregnant women with pregnancy-related pelvic pain: A parallel-groups clinical study
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria for pregnant women with pelvic pain: 1. Pregnant women with pelvic pain, between the ages of 25 and 35 who are experiencing their first pregnancy. 2. Pelvic pain in these women, should be from 18 weeks onwards, with pain in the sacroiliac joints and/or pubic area. 3. The result of two tests from the mentioned tests (posterior pelvic pain stimulation test, Patrick Faber's test, Trendelenburg test, and active straight leg test) should be positive during the clinical examination. 4. According to the VAS assessment, the rate of pelvic pain in pregnant women should be higher than 3 out of10. Inclusion criteria for healthy pregnant women without pelvic pain: 1. Healthy pregnant women between the ages of 25 and 35 who are experiencing their first pregnancy.
Exclusion criteria:
Exclusion criteria for pregnant women with pelvic pain: 1. Pelvic pain and low back pain before pregnancy. 2. Red flags symptoms 3. Multiple pregnancies 4. Pregnancies with complications and other diseases such as systemic diseases. Exclusion criteria for healthy pregnant women without pelvic pain: 1. Pelvic pain and low back pain before and after pregnancy. 2. During the clinical examination, even if one of the tests for posterior pelvic pain stimulation, Patrick Fabers, the modified Trendelenburg test and, the active straight leg test are positive. 3. Red flag symptoms. 4. Multiple pregnancies. 5. Pregnancies with complications and other diseases such as systemic diseases.
Age
From **25 years** old to **35 years** old
Gender
Female

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **51**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment of study groups is a blocking method. The method of doing it is as follows. The size of each block or the number of people in each block is 3 people. Meanwhile, three groups in this study (17 Healthy Pregnant or HP pregnant women, 17 pregnant women with pelvic pain with manual (control group or C) and,17 pregnant women with pelvic pain with the pelvic girdle (group) There is an Intervention Group or IG, the arrangement of the members of each block as (IG, HP, C), (IG, C, HP), (C, IG, HP), (C, HP, IG), (HP, C, IG), (HP, IG, C) In the next step, these 6 states are written on paper and poured into a container.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Esfahan University of Medical Sciences, Isfahan, Iran
Street address
School of Rehabilitation, Esfahan University of Medical Sciences, Hezar Jerib St., Esfahan.
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Approval date
2022-05-02, 1401/02/12
Ethics committee reference number
IR.MUI.NUREMA.REC.1401.030

Health conditions studied

1

Description of health condition studied
Pelvic pain in pregnant women (in the posterior pelvic area)
ICD-10 code
R10.2
ICD-10 code description
Pelvic and perineal pain

Primary outcomes

1

Description

Surface electromyography

Timepoint

In the first session, all participants participate in an electromyographic evaluation once. In the same session, after wearing the pelvic belt, the intervention group performs an electromyography evaluation. In the intervention group, the pelvic belt is worn during awakening and during the day for two hours and thirty minutes, for 14 days. The control group (receiving the manual) and the intervention group perform electromyographic evaluations on day 14.

Method of measurement

The muscles are evaluated in a standing position, through superficial electrodes in the distal and proximal pelvic muscles (posterior thigh muscles (long biceps and tendon muscle), gluteus maximus, multifidus muscles (level two L1 and L5) and, internal oblique muscles are examined. The signals recorded by the kinesiological EMG ME 6000 electromyography device are stored on the laptop through the Mega Win software. After deleting the beginning and end of the recorded values, the duration is 10 seconds out of 20 seconds. Information processing is done by MATLAB software.

2

Description

(Intensity of pain) Visual Analogue Scale

Timepoint

In the first session, all participants will be assessed for pain intensity once. In the same session again, after wearing the pelvic belt, the intervention group is evaluated. In the intervention group, the pelvic belt is worn during awakening and during the day for two hours and thirty minutes, for 14 days. The control group (receiving the manual) and the intervention group perform electromyographic evaluations on day 14.

Method of measurement

It consists of a 10 cm line, which is placed horizontally on a piece of paper. A dot is placed on it at each end. One point of this line indicates "no pain", and the other point indicates "maximum perceived pain intensity". Individuals assess their perceived pain intensity by marking on this horizontal scale line. The distance from the point of no pain to this person-marked mark is measured by a ruler. This symptom is used as the overall score of pain intensity. This distance is measured in millimeters to determine the scores from 0 to 100. The study participant is asked to indicate the pain they are currently experiencing in a vertical line on this scale.

3

Description

Pelvic Girdle Questionnaire

Timepoint

In the first session, all participants will have a pelvic pain questionnaire once. In the same session again, after wearing the pelvic belt, the intervention group is evaluated. In the intervention group, the pelvic belt is worn during awakening and during the day for two hours and thirty minutes, for 14 days. The control group (receiving the manual) and the intervention group perform the evaluations on the 14th day.

Method of measurement

The pelvic pain questionnaire is used as an advanced specialized tool to assess patients with pelvic girdle pain. This questionnaire includes items related to the activity, participation and physical symptoms of the person. The pelvic girdle questionnaire is suitable for both pregnant and post-pregnancy women with pelvic pain. Participants are asked to carefully complete the questionnaire form.

4

Description

Pain Catastrophizing Scale

Timepoint

In the first session, all participants will be assessed once on the Catastrophic Pain Scale questionnaire. In the same session again, after wearing the pelvic belt, the intervention group is evaluated. In the intervention group, the pelvic girdle is worn during awakening and during the day for two hours and thirty minutes, for 14 days. The control group (receiving the manual) and the intervention group perform the evaluations on the 14th day.Participants are asked to carefully complete the questionnaire form.

Method of measurement

The Catastrophizing Pain Scale Questionnaire, a 13-item scale that assesses patients' catastrophic thoughts and behaviors when faced with pain, consists of three subscales of mental rumination, exaggeration, and despair. Participants are asked to carefully complete the questionnaire form.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group includes 17 pregnant women with pelvic pain related to pregnancy. This group is given a slim and flexible pelvis. This belt should be located in the pubic area or pubis. First, women adjust the pelvic belt on their body, and then, they adjust the pelvic belt pressure on both sides through Velcro elastic systems. This pelvic belt is adaptable for different stages of pregnancy due to the Velcro and elastic system. On the first day, according to the waist circumference of the person participating in the study, the appropriate size is selected. The person is taught how to wear a belt. The pelvic girdle of the intervention group is worn during awakening and during the day for two hours and thirty minutes, for 14 days.

Category

Treatment - Devices

2

Description
Control group: This group includes 17 pregnant women with pelvic pain related to pregnancy. These people are given a logbook. Control group members must follow the instructions in the manual for 14 days. The information in this guide includes recommendations for identifying the factors that contribute to pelvic pain and, appropriate lifestyle (posture correction while sitting, walking and sleeping) to prevent and reduce pelvic pain in pregnant women.

Category
Rehabilitation

3

Description
Comparison group: This group includes healthy women without pelvic pain, who have no intervention. This group is present in this study only to compare surface electromyography evaluations of muscles with the intervention group.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Hospital

Full name of responsible person
Dr. Mahmonir Jafari Harandi

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Sponsors / Funding sources

1

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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Ebrahim Sadeghi-Demneh

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Associate Professor, Director of Prosthetics & Orthotics Department

Latest degree
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Other areas of specialty/work
Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Study information (other than personal information) is shared with other researchers.
When the data will become available and for how long
Information is shared after the results are printed or summarized.
To whom data/document is available
Information will be shared for academic purposes only.
Under which criteria data/document could be used
Information is shared to teach and research applicants.
From where data/document is obtainable
Individuals can request information from the person in charge.
What processes are involved for a request to access data/document
Requests should be sent by email (sadeghi@rehab.mui.ac.ir).
Comments