Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Effectiveness of Lumbar support on Pain, Disability, and Motor Control in Women with Postpartum Pelvic Girdle Pain: a Randomized Controlled Trial

Protocol summary

Study aim

The aim to investigate whether using lumbar support reduces pain in women with pregnancy-related PPGP versus control.

Design

This study will be a prospective randomized-controlled clinical trial with three parallel groups. Based on previous study, the target sample size of 84 will be randomly assigned into control or intervention groups by block randomization method.The assessor will perform randomization with a Random Allocation Software.

Settings and conduct

Data will be collected from the obstetric outpatient clinics of Isfahan University of Medical Sciences under supervision of Gynecologist. The examiner will check the inclusion and exclusion criteria to confirm the eligible subjects. Participants will enroll in one of the study groups based on block randomization. Group one will receive pelvic belt, lumbar support will be given to group two, and group three will receive education leaflet. Outcomes will measure in evaluation day, 4-week and 5-week after study began.

Participants/Inclusion and exclusion criteria

Inclusion criteria: (1) Primipara women with natural delivery (one month before) (2) Age between 18 and 45 years (3) self-reported unilateral PPGP confirmed with examiner Exclusion criteria: (1) The presence of lower back or pelvic pain before pregnancy (2) uUsing any other conservative treatment for pain relief during the study

Intervention groups

They will be randomly assigned with equal allocation to one of 3 groups: (A) pelvic (narrower) support, (B) lumbar (broader) support, and (C) control group (patient-education leaflet).

Main outcome variables

Overall pain; Effort score during active straight leg raise; Maximum isometric hip flexion force; Maximum isometric trunk rotation and hip external rotation force; Joint position reproduction of hip abduction; Activity limitation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200601047625N1**
Registration date: **2023-06-19, 1402/03/29**
Registration timing: **prospective**

Last update: **2023-06-19, 1402/03/29**
Update count: **0**

Registration date

2023-06-19, 1402/03/29

Registrant information

Name

Fahimeh Sadat Jafarian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Lumbar support on Pain, Disability, and Motor Control in Women with Postpartum Pelvic Girdle Pain: a Randomized Controlled Trial

Public title
Effectiveness of Lumbar support on Pain in Postpartum Pelvic Pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Primipara women who experienced natural delivery (one month before) Self-reported pregnancy-related posterior pelvic girdle pain (PPGP) A pain score of at least 40 out of100 mm on the visual analog scale (VAS) A score of higher than 2 out of 5 on a 6-point Likert scale for perceived effort during the ASLR test Age between 18 and 45 years Confirm the unilateral sacroiliac joint pain
Exclusion criteria:
The presence of lower back or pelvic pain before pregnancy History of any fracture in the pelvis and lower extremities History of spine, pelvis, and lower extremity surgery Neurological diseases Limb length discrepancy Congenital anomaly in the spine, pelvis, and lower extremities Using any other conservative treatment for pain relief during the study
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Intervention allocation will be carried out by block randomization method such that an equal number will be assigned to each study group. Once participants are confirmed to be eligible, they will be randomly assigned to one of three study groups with equal allocation at a 1:1:1 ratio (control or pelvic belt or lumbar support). Based on block randomization (each block, n=6), the examiner will perform randomization with a Random Allocation Software. Examiner will choose blocks randomly and will allocate participants according to the serial assignment.
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
Ethical committee of Isfahan University of Medical Sciences
Street address
Postal code: 81746-73461, Hezar Jerib St., Isfahan
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2022-09-12, 1401/06/21
Ethics committee reference number
IR.MUI.NUREMA.REC.1401.076

Health conditions studied

1

Description of health condition studied
Pregnancy-related posterior pelvic girdle pain (PPGP)
ICD-10 code
R10.2
ICD-10 code description
Pelvic and perineal pain

Primary outcomes

1

Description
Pain severity
Timepoint
The pain score will be measured at four time points in intervention groups: (1) baseline, (2) immediately after the intervention, (3) four-week after the interventions began, and (4) one-week after discontinuing the interventions. In control group, the pain score will be measured at three time points: (1) first session, (2) four-week after the study began, and (3) five-week after the study began.
Method of measurement
She will score her pain by visual analog scale (VAS) ranged from 0 to 10; zero means no pain, and 10 presents the worst imaginable pain.

Secondary outcomes

1

Description

Effort score during active straight leg raising test

Timepoint

The effort score will be measured at four time points in intervention groups: (1) baseline, (2) immediately after the intervention, (3) four-week after the interventions began, and (4) one-week after discontinuing the interventions. In control group, the effort score will be measured at three time points: (1) first session, (2) four-week after the study began, and (3) five-week after the study began.

Method of measurement

Subjects will score the difficulty to perform the test on a 6-point Likert scale (ranging from 0 to 5); zero presents no difficulty, and five means unable to do.

2

Description

Maximum isometric hip flexion force

Timepoint

The maximum isometric hip flexion force will be measured at four time points in intervention groups: (1) baseline, (2) immediately after the intervention, (3) four-week after the interventions began, and (4) one-week after discontinuing the interventions. In control group, the maximum isometric hip flexion force will be measured at three time points: (1) first session, (2) four-week after the study began, and (3) five-week after the study began.

Method of measurement

Digital force gauge (Digital Force Gauge, SF-500, Akurasi, 0.001kg) will be attached to the metal bar and adjusted in which is located just above the ankle. The subject will be asked to raise her involved leg and compress the force gauge probe while the leg is still lying on the table.

3

Description

Maximum isometric hip external rotation force

Timepoint

The maximum isometric hip external rotation force will be measured at four time points in intervention groups: (1) baseline, (2) immediately after the intervention, (3) four-week after the interventions began, and (4) one-week after discontinuing the interventions. In control group, the maximum isometric hip external rotation force will be measured at three time points: (1) first session, (2) four-week after the study began, and (3) five-week after the study began.

Method of measurement

Subjects will perform isometric muscle strength testing for hip external rotation using digital force gauge and a stabilization strap. The subject will be asked to pull her leg inward with maximal effort.

4

Description

Maximum isometric trunk rotation force

Timepoint

The maximum isometric trunk rotation force will be measured at four time points in intervention groups: (1) baseline, (2) immediately after the intervention, (3) four-week after the interventions began, and (4) one-week after discontinuing the interventions. In control group, the maximum isometric trunk rotation force will be measured at three time points: (1) first session, (2) four-week after the study began, and (3) five-week after the study began.

Method of measurement

This outcome will be measured using digital force gauge (Model: SF-500, Akurasi, 0.001kg) subject will be positioned on the chair in the upright sitting position. The subjects will be asked to rotate her trunk toward the opposite side and exert isometric force to force gauge probe. This test will perform again for other site.

5

Description

Joint position reproduction (JPR) of hip abduction

Timepoint

The Joint position reproduction (JPR) of hip abduction will be measured at four time points in intervention groups: (1) baseline, (2) immediately after the intervention, (3) four-week after the interventions began, and (4) one-week after discontinuing the interventions. In control group, this outcome will be measured at three time points: (1) first session, (2) four-week after the study began, and (3) five-week after the study began.

Method of measurement

The Joint position reproduction (JPR) of hip abduction will be measured using the active JPR while standing. Three reflective markers will be attached to the apex of the iliac crest, greater trochanter, and lateral femur epicondyle. The movement of the reflective markers will be recorded using a Canon camera (EOS-500D, DS126231) placed behind the participant at a distance of 2.5 m.The camera’s tracking angles will be analyzed by Kinovea software (0.9.2, GPLv2 license, 2019).

6

Description

Disability score

Timepoint

Disability score will be measured at three time points in intervention groups: (1) first session, (2) four-week after the interventions began, (3) one-week after discontinuing the interventions. In control group, this outcome will be also measured at three time points: (1) first session, (2) four-week after the study began, and (3) five-week after the study began.

Method of measurement

The Persian version of ODI will be used to quantify disability in women with post-partum pelvic pain. The tool is a 10-item questionnaire which mainly questioning about pain intensity related to the daily activities.

Intervention groups

1

Description
Intervention group: Pelvic belt. The participants will receive a pelvic belt. It is made from breathable textile material to provide comfort for the participant. The pelvic belt will be an adjustable strap (width 10-15cm) fastened just under ASIS. Belt will be available in different sizes and fitted individually by a trained examiner to provide the best possible personalized orthosis. The fitting method and the minimum expected using time (4 hours a day) of orthosis will be explained and demonstrated to all users.

Category
Treatment - Devices

2

Description
Intervention group: lumbar/pelvic support. The lumbar/pelvic support consists of a pelvic belt attached to the lumbar corset. The support has a 25-cm width anteriorly and extends from the xiphoid process to the pelvis. It has a 35-cm width posteriorly and extends down from the lower angle of the scapula to gluteal prominences. It has 3 panel with 10 cm width: one transverse panel placed inferior to ASIS, and two other crossed panels positioned on abdominal muscles. Support will be available in different sizes and fitted individually by a trained examiner to provide the best possible personalized orthosis. The fitting method and the minimum expected using time (4 hours a day) of orthosis will be explained and demonstrated to all users.

Category
Treatment - Devices

3

Description
Control group: Education leaflet. control group will receive only a patient education leaflet containing advice on strengthening exercises, comfortable positions (standing, walking, sleeping, and lifting), and other practical information.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital

Full name of responsible person
Dr Mahmonir Jafari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Masoud Rismanchian

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technology@mui.ac.ir

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
Fahimeh Sadat Jafarian

Position
PhD student

Latest degree
Master

Other areas of specialty/work

Rehabilitation management

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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
Undecided - It is not yet known if there will be 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The study data (excluding the personal details) can be shared with other researchers or systematic reviewers.

When the data will become available and for how long
Data will be shared once findings are come up or summary date is published.

To whom data/document is available
Data will be shared personally and for academic purposes only.

Under which criteria data/document could be used
Data will be shared for teaching or research. Fahimeh Sadat Jafarian (correspondence) will review the requests.

From where data/document is obtainable
People can sent their request to the correspondence and obtain the data.

What processes are involved for a request to access data/document
Request should be sent through an email (fahimejafarian@yahoo.com).

Comments