Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effects of Lumbosacral Orthosis on the Pain Management and Load Transfer of the Sacroiliac Joint in Women with Postpartum Pelvic Pain: A Parallel-Group Clinical Study

Protocol summary

Study aim

This study aimed to compare the effectiveness of sacroiliac belt as an usual intervention and new-designed lumbosacral orthosis (LSO) on pain management and load transfer in women with post-partum posterior pelvic pain.

Design

This study will be a prospective randomized-controlled clinical trial with two parallel groups. Based on previous study, the target sample size of 60 will be randomly assigned into control or intervention group by block randomization method.

Settings and conduct

Eligible subject will be recruited from the obstetric-outpatient clinics of Isfahan University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: (1) Primipara women, natural delivery (one-month before) (2) Self-reported pregnancy-related pelvic pain (3) Pain score of at least 30 (4) Effort score of higher than 2 (5) Age between 18 and 45 years (6) Ability to read and write in Persian language (7) Unilateral sacroiliac joint pain Exclusion criteria: (1) Presence of low back and/or pelvic pain before pregnancy (2) History of spine, pelvis, and lower extremities surgery (3) Limb length discrepancy (4) Congenital anomaly in the spine, pelvis, and lower extremities (5) History of any fracture in lower extremities (6) Using any other conservative treatment for pain relief (7) Symptoms of pathological disease like fever and involuntary weight loss (8) Score of pain ≥ 8 (9) Neurological, inflamatory diseases

Intervention groups

Two groups will be considered for this study. Control and intervention group will receive sacroilaic belt and lumbosacral orthosis (LSO) , respectively

Main outcome variables

Pain during active straight leg raise (ASLR) Effort score during ASLR Maximum isometric hip flexion force Maximum isometric trunk rotation force Maximum isometric hip external rotation force Joint position reproduction (JPR) of hip abduction Disability score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150210021034N11**
Registration date: **2021-05-31, 1400/03/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-31, 1400/03/10**
Update count: **0**

Registration date

2021-05-31, 1400/03/10

Registrant information

Name
Ebrahim Sadeghi-Demneh
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Lumbosacral Orthosis on the Pain Management and Load Transfer of the Sacroiliac Joint in Women with Postpartum Pelvic Pain: A Parallel-Group Clinical Study

Public title

The Effects of Lumbosacral Orthosis on Pain in Postpartum Pelvic Pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Primipara women experienced natural delivery (one-month before) Self-reported pregnancy-related pelvic pain A pain score of at least 30 out of 100 on the visual analog scale (VAS) A score of higher than 2 out of 5 on a 6-point Likert scale Age between 18 and 45 years Ability to read and write in Persian language Confirm the unilateral sacroiliac joint pain

Exclusion criteria:

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

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 participant is confirmed eligible, she will be randomly assigned to either pelvic belt (control) or LSO (intervention) group (ratio 1:1). Based on block randomization (each block, n=4), there will be 6 possible ways to assign participants to a block: 1122, 1212, 1221, 2112, 2121, 2211 (1= pelvic belt, 2= LSO). Examiner will choose blocks randomly and will allocate participants according to the serial assignment.

Blinding (investigator's opinion)

Single blinded

Blinding description

In present study, only researcher will be aware about the intervention allocated to each participant. Examiner will choose blocks randomly and will allocate participants according to the serial assignment.

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, Isfahan, Iran

Street address

Hezar Jerib street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2021-05-24, 1400/03/03

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.007

Health conditions studied

1

Description of health condition studied

Pregnancy related sacroiliac posterior pelvic pain

ICD-10 code

R10.2

ICD-10 code description

Pelvic and perineal pain

Primary outcomes

1

Description

Pain severity

Timepoint

Pain score will be measured at three stages: a) The first session is to assess the outcome measure at baseline and the immediate effect of interventions. b) The second session will be a follow-up four-week after the initial assessments. c) The third session will measure at one-week after discontinuing intervention.

Method of measurement

She will score her pain during the test by visual analog scale (VAS) ranged from 0 to 10; zero means no pain, and 10 presents the worst imaginable pain.

2

Description

Effort score during active straight leg raising test

Timepoint

Effort score will be measured at three stages: a) The first session is to assess the outcome measure at baseline and the immediate effect of interventions. b) The second session will be a follow-up four-week after the initial assessments. c) The third session will measure at one-week after discontinuing intervention.

Method of measurement

Participants 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

3

Description

Maximum isometric hip flexion force

Timepoint

Effort score will be measured at three stages: a) The first session is to assess the outcome measure at baseline and the immediate effect of interventions. b) The second session will be a follow-up four-week after the initial assessments. c) The third session will measure at one-week after discontinuing intervention.

Method of measurement

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 participant will be asked to raise her involved leg and compress the force gauge probe while the leg is still lying on the table.

4

Description

Maximum isometric hip external rotation force

Timepoint

Effort score will be measured at three stages: a) The first session is to assess the outcome measure at baseline and the immediate effect of interventions. b) The second session will be a follow-up four-week after the initial assessments. c) The third session will measure at one-week after discontinuing intervention.

Method of measurement

Participants will undergo isometric muscle strength testing for hip external rotation using digital force gauge and a stabilization strap. The subject will be instructed to pull her leg inward with maximal effort until force value is displayed on the force gauge.

5

Description

Maximum isometric trunk rotation force

Timepoint

Effort score will be measured at three stages: a) The first session is to assess the outcome measure at baseline and the immediate effect of interventions. b) The second session will be a follow-up four-week after the initial assessments. c) The third session will measure at one-week after discontinuing intervention.

Method of measurement

This variable will be measured using digital force gauge (Model: SF-500, Akurasi, 0.001kg) Participant 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.

6

Description

Joint position reproduction (JPR) of hip abduction

Timepoint

Effort score will be measured at three stages: a) The first session is to assess the outcome measure at baseline and the immediate effect of interventions. b) The second session will be a follow-up four-week after the initial assessments. c) The third session will measure at one-week after discontinuing intervention.

Method of measurement

This variable will be measured while subject standing. Three passive markers will be attached to the apex of the iliac crest, greater trochanter, and lateral femur epicondyle. Movement kinematics of markers will be captured using a Canon camera (EOS-500D, DS126231, Japan) placed behind the participant at a distance of 2.5m. The camera’s tracking angles will be analyzed by Kinovea software (0.9.2, GPLv2 license, 2019).

7

Description

Disability score

Timepoint

Effort score will be measured at three stages: a) The first session is to assess the outcome measure. b) The second session will be a follow-up four-week after the initial assessments. c) The third session will measure at one-week after discontinuing intervention.

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.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Lumbosacral orhosis (LSO) The participants will receive LSO. It is made from breathable textile material to provide comfort for the participant. The LSO will provide circumferential pressure on the torso and pelvic area. The LSO includes four semi-rigid bars inserted vertically to the posterior part to support the stability of the lower back. Three anterior panels (width about 10cm) will be incorporated in the orthosis. Transverse compression panel will be fastened just under anterior superior iliac spine (ASIS) in pelvic belt location. Two diagonal straps are obliquely fastened around the abdominal wall (like oblique muscle orientation) .Both

orthoses will be available in different sizes and fitted individually by a trained examiner to provide the best possible personalized orthosis.

Category

Treatment - Devices

2

Description

Control 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 of orthosis will be explained and demonstrated to all users.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital

Full name of responsible person
Dr. Elaheh zarean

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Esfarayen University of Medical Sciences

Full name of responsible person
Ebrahim Sadeghi

Position
Associate professor

Latest degree
Ph.D.

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. Dr Sadeghi (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 (sadeghi@rehab.mui.ac.ir).

Comments