Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The immediate effects of pelvic compression belt with a textured sacral pad on the sacroiliac function in the pregnant women with lumbopelvic pain

Protocol summary

Study aim

To investigate the immediate effects of a pelvic belt with a textured sacral pad in pregnant women with lumbopelvic pain

Design

This is a randomized crossover study in which 28 pregnant women with pelvic pain diagnosed by an obstetrics and gynecology specialist pelvic symptoms according to specific diagnostic criteria. ،There are three interventions and the order of intervention and testing conditions are randomized. This is a single blind study and in data analysis people are unaware of group designations.

Settings and conduct

This study run in Alzahra hospital, Isfahan, Iran. The testing protocol was started after pelvic belts were fitted and 5 minutes acclimatization. Participants were given about 10 minutes rest before the crossed-over to the next pelvic belt. Pelvic belt effects were investigated under three random conditions: without pelvic belt application, with a pelvic belt, and adding a textured sacral pad inside the same pelvic belt.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Increase in the pain intensity with changing the position and decrease in the pain with resting Exclusion Criteria: History of trauma or surgery in the lower back or pelvis, history of sacroiliac pain before the first pregnancy, signs of neural radiculopathy, or presence of visceral or vaginal pains

Intervention groups

Control Group: no pelvic belt (control), intervention group 1: routine pelvic belt, and intervention group 2: Pelvic belt with sacral pad

Main outcome variables

Outcome measures: the hip proprioception, effort during single leg raising, and maximum isometric hip flexion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150210021034N2**
Registration date: **2019-07-18, 1398/04/27**
Registration timing: **retrospective**

Last update: **2019-07-18, 1398/04/27**
Update count: **0**

Registration date

2019-07-18, 1398/04/27

Registrant information

Name

Ebrahim Sadeghi-Demneh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

2017-04-21, 1396/02/01

Actual recruitment end date

2017-08-21, 1396/05/30

Trial completion date

2017-09-21, 1396/06/30

Scientific title
The immediate effects of pelvic compression belt with a textured sacral pad on the sacroiliac function in the pregnant women with lumbopelvic pain

Public title
Pelvic Belt in pregnant women
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Increase in pain intensity with changing position
Decrease in pain intensity with resting
Exclusion criteria:
History of trauma or surgery in the lower back or pelvis
History of sacroiliac pain before the first pregnancy Signs of radiculopathy Presence of visceral or vaginal pains
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **25**
Actual sample size reached: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
This is a randomized controlled crossover study, during which participants acted as their controls (no pelvic belt) and compared to two pelvic belts (including a routine pelvic belt and pelvic belt with a textured sacral pad) in a single session.The order of intervention and testing conditions were randomized and determined by taking a concealed draw from a hat.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Isfahan University of Medical Sciences
Street address
Hezar Jerib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2016-05-21, 1395/03/01
Ethics committee reference number
IR.MUI-REC-1395.3.318

Health conditions studied

1

Description of health condition studied
Pelvic pain
ICD-10 code
R10.2
ICD-10 code description
Pelvic and perineal pain

Primary outcomes

1

Description
Hip proprioception
Timepoint
This outcome is measured immediately after fastening the pelvic belt.
Method of measurement
Hip proprioception is evaluated by measurement of the active angle reproduction in hip abduction. The participant's eyes are closed during proprioceptive testing. Participate are positioned supine and instructed to abduct the thigh with an extended knee until it reached 20 degrees abduction at the hip and the assessor indicated "stop". They are asked to concentrate on this target angle for 5 seconds and memorize it. The lower limb passively returned to the starting position by the assessor. Participants attempted to reproduce the target angle with an active thigh abduction. Each test is repeated three times for each side, and angle error was calculated as a mean absolute error and used as the proprioceptive outcome measure.

2

Description
Maximum isometric hip flexion
Timepoint
This outcome is measured immediately after fastening the pelvic belt.
Method of measurement
The maximum isometric hip flexion is measured with an extended knee at the end of active single leg raising test (20 cm above the table). A non-elastic 5 cm width belt restricted the hip flexion once the ankle reached 20 cm height and the force that applied to the belt was recorded using a digital force gauge.

3

Description
Effort in active single leg raising
Timepoint
This outcome is measured immediately after fastening the pelvic belt.
Method of measurement
Participants are asked to rate their effort in performing active single leg raising on a six-point Likert scale: 0=not difficult, 1=minimally difficult, 2=somewhat difficult, 3=fairly difficult, 4=very difficult, and 5=unable to perform.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: without pelvic belt
Category
N/A

2

Description
Intervention group 1: Routine pelvic belt. The belt used in this study was a non-stretchable material made of nylon webbing, which was about 5 cm wide at the anterior and 7 cm at the posterior side. Four different sizes of the belt were available, were selected according to the pelvic circumference of each participant. The belt was fastened with a Velcro and positioned just below the anterior superior iliac spine. The compression force applied on the fastening Velcro was set at 50N and controlled within the study conditions using a force measurement apparatus.
Category
Rehabilitation

3

Description
Intervention group2: Pelvic belt with textured sacral pad. The sacral pad attached to the pelvic belt (Intervention 2) was an equilateral triangle (each side: 12 cm) made by silicone rubber (thickness of base: 1.5cm, shore value: A40). Twelve convex circular spikes (with 1cm height) were incorporated over the sacral pad; the pick-to-pick distance of the spikes was 2 cm
Category
Rehabilitation

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
Esfahan University of Medical Sciences
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

Esfahan University of Medical Sciences

Full name of responsible person

Ebrahim Sadeghi-Demneh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

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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

The study data (excluding the personal details) can be shred with other researchers or systematic reviewers.

When the data will become available and for how long

No time limit is set.

To whom data/document is available

No specific limitation is considered.

Under which criteria data/document could be used

No terms and conditions is considered for sharing the data.

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 can be sent through an email.

Comments