

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 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 committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib

City

Isfahan

Province

Isfahan

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. Participants 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

Shaghayegh Haghjov

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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 shared 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 send 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