Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The design and construction of the modified lumbar pelvic belt and compares its effect on back and pelvic muscle activity and pain with the conventional pelvic belt in pregnant women

Protocol summary

Study aim
The design and construction of the modified lumbar pelvic belt and compares its effect on back and pelvic muscle activity and pain with the conventional pelvic belt in pregnant women

Design
According to clinical trial studies, participants in the study (48 people) were randomly divided into three groups. One group will be given a common pelvic girdle, the other group will be given a modified pelvic girdle belt made by the research team, to the third group none of the belts Will not be prescribed (control group).

Settings and conduct
This study will be performed in Kosar specialized and sub-specialized clinic in Arak. Pelvic Girdle, SF36, DIO, and pain intensity questionnaires will be used. The muscular activity of the lumbar and pelvic muscles will be evaluated during the ASLR, trunk flexion extension, sitting-standing up, and walking in different positions using the belts. Blinding is one-sided

Participants/Inclusion and exclusion criteria
Inclusion criteria include: Pregnant women from the 20th week of pregnancy Pregnant women with moderate to severe pain Age under 40 years Single pregnancy Clinical diagnosis of low back pain or pelvic pain based on what people say Criteria for non-entry include: Pregnant women with a history of surgery on the spine or pelvis Pregnant women with a history of back pain and pelvic pain before pregnancy Systemic diseases Any signs of high-risk pregnancy Twin pregnancy Depression Neurological diseases Common use of NSAIDs or any medication containing corticosteroids in the last 30 days

Intervention groups
The first intervention group will be given a common pelvic girdle, the second intervention group will be given a modified pelvic girdle made by the research team, and the control group will not be given any of the belts.

Main outcome variables
Lumbar or Pelvic pain; Lumbar muscle activity; Pelvic muscle activity; Function; Quality of life

General information

Reason for update
Add a new variable

Acronym

IRCT registration information
IRCT registration number: **IRCT20200925048833N1**
Registration date: **2020-12-23, 1399/10/03**
Registration timing: **prospective**

Last update: **2022-09-10, 1401/06/19**
Update count: **1**

Registration date
2020-12-23, 1399/10/03

Registrant information

Name
Zhaleh Heidari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-21, 1400/01/01

Expected recruitment end date
2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The design and construction of the modified lumbar pelvic belt and compares its effect on back and pelvic muscle activity and pain with the conventional pelvic belt in pregnant women

Public title

The effect of modified lumbar pelvic belt on back and pelvic muscle activity and pain in pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women from the 20th week of pregnancy Pregnant women with moderate to severe pain (Pain intensity 4 and above in VAS) Age under 40 years Single pregnancy Clinical diagnosis of low back pain or pelvic pain based on the individual's own statement, negative answer to research questions and positive result of at least one of the following tests:1. Patrick's/Faber Test 2. posterior pelvic pain provocation 3.Modified Trendelenberg Test with direct palpation of the symphysis pubis 4.Active straight leg raise test

Exclusion criteria:

Pregnant women with a history of surgery on the spine or pelvis Pregnant women with a history of back pain and pelvic pain before pregnancy Systemic diseases such as restrictive lung diseases, heart disease and diabetes Any signs of high-risk pregnancy Twin pregnancy Depression Neurological diseases Common use of NSAIDs or any medication containing corticosteroids in the last 30 days

Age

To **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

According to clinical trial studies, participants in the study are randomly divided into three groups (first intervention, second intervention and control).The method of allocating samples in control and intervention groups is done in a simple randomization based on the lottery of sample members (individual randomization unit).In this method, using a table of random numbers, one of the numbers is touched and moved in one of the predetermined directions, each member of the sample whose number was selected, will be divided into one of the study groups, respectively. .

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 University of Social Welfare and Rehabilitation Sciences

Street address

University of Social Welfare and Rehabilitation Sciences, kodakyar Ave, daneshjoo Blvd, Evin, Tehran, Iran

City

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Province

Tehran

Postal code

1985713834

Approval date

2020-09-12, 1399/06/22

Ethics committee reference number

IR.USWR.REC.1399.161

Health conditions studied

1

Description of health condition studied

Low back pain

ICD-10 code

M54.05

ICD-10 code description

Panniculitis affecting regions of neck and back, thoracolumbar region

2

Description of health condition studied

Pelvic pain

ICD-10 code

R10.2

ICD-10 code description

Pelvic and perineal pain

Primary outcomes

1

Description

lumbar or pelvic Pain

Timepoint
At the beginning of the study and three weeks after using the belts
Method of measurement
Visual Analogue Scale

2

Description
function
Timepoint
At the beginning of the study and three weeks after using the belts
Method of measurement
Pelvic Girdle Questionnaire, Disability Index Oswestry Questionnaire

3

Description
lumbar muscle activity
Timepoint
At the beginning of the study and three weeks after using the belts
Method of measurement
Surface Electromyography Device

4

Description
pelvic muscle activity
Timepoint
At the beginning of the study and three weeks after using the belts
Method of measurement
Surface Electromyography Device

5

Description
Quality of life
Timepoint
At the beginning of the study and three weeks after using the belts
Method of measurement
SF36 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Common pregnancy pelvic belt with common advice For individuals, demographic questionnaires, visual analogue scale, Pelvic Girdle questionnaire to assess pain, activity, and disability, Disability Index Oswestry questionnaire to assess performance, and SF36 questionnaire to evaluate the quality of life will be completed. Also, the muscular activity of the back and pelvis is performed and recorded using a surface electromyographic device in the positions of Active straight leg raise test, trunk flexion and extension, sitting and standing up, and walking. As a result, muscle activity is assessed immediately before the belt is fastened and after the belt is administered. After three weeks of using the belts for 4 to 5 hours daily and during the activity, the pain intensity Pain Intensity Scale, Pelvic Girdle questionnaire, Disability Index Oswestry, and SF36 are completed for them again. Also, the muscular activity of the lumbar and pelvic muscles is performed and recorded without using and using the belt in all previous cases.
Category
Rehabilitation

2

Description
Intervention group 2: Pregnancy lumbar and pelvic belt made by the research team with common advice For individuals, demographic questionnaires, visual analogue scale, Pelvic Girdle questionnaire to assess pain, activity, and disability, Disability Index Oswestry questionnaire to assess performance, and SF36 questionnaire to evaluate the quality of life will be completed. Also, the muscular activity of the back and pelvis is performed and recorded using a surface electromyographic device in the positions of Active straight leg raise test, trunk flexion, and extension, sitting and standing, and walking. As a result, muscle activity is assessed immediately before the belt is fastened and after the belt is administered. After three weeks of using the belts for 4 to 5 hours daily and during the activity, the pain intensity Scale, Pelvic Girdle questionnaire, Disability Index Oswestry, and SF36 are completed for them again. Also, the muscular activity of the lumbar and pelvic muscles is performed and recorded without using and using the belt in all previous cases.
Category
Rehabilitation

3

Description
Control group: Common advice For individuals, demographic questionnaires, visual analogue scale, Pelvic Girdle questionnaire to assess pain, activity, and disability, Disability Index Oswestry questionnaire to assess performance, and SF36 questionnaire to evaluate the quality of life will be completed. Also, the muscular activity of the back and pelvis is performed and recorded using a surface electromyography device in the positions of - active straight leg raise test - trunk flexion and extension - sitting and standing - walking. Then They are given common advice on preventing back and pelvic pain. After three weeks, they complete the Pain Intensity Scale, the Pelvic Girdle Questionnaire, the Disability Index Oswestry, and SF36. Also, the muscular activity of the lumbar and pelvic muscles is performed and recorded in all previous cases.
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Kowsar specialized and sub-specialized clinic

Full name of responsible person
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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
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Zhaleh Heidari

Position
PhD Student

Latest degree
Master

Other areas of specialty/work
Orthosis and Prosthesis

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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

Yes - There is a plan to make this available

Title and more details about the data/document

All of the above will be published in the article.

When the data will become available and for how long

There will be access after the article is published.

To whom data/document is available

After the article is published, researchers can access it.

Under which criteria data/document could be used

Other researchers, obstetricians, therapists in the field of medicine and rehabilitation can use this research after the publication of the article.

From where data/document is obtainable

Refer to the published articles of this research.

What processes are involved for a request to access data/document

Refer to the published articles of this research.

Comments