

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison between two types of treatment in pelvic girdle pain in pregnancy: Abdomino lumbo pelvic belt and exercise therapy.

Protocol summary

Summary

132 healthy pregnant women with pelvic girdle pain and pregnancy date 20 - 32 weeks will be recruited. Other eligibility criteria: 1- Mono fetus. 2- Pelvic girdle pain had been diagnosed with history, physical examination and specific tests. 3- Contraindications of exercise in pregnancy should not be existed. 4- Systemic diseases should not be existed such as: restrictive lung diseases, heart diseases. Exclusion criteria: 1. contraindications of exercise in pregnancy 2. If participants don't come back after 3 and 6 weeks of intervention. 3. If participants don't use belt and exercise regularly. The tool for data collection is a questionnaire that gathers: demographic data of participants, history of pregnancy, and information about pelvic girdle pain starting from 1 to 2 weeks before referral to the center. For patients with pain in symphysis pubis special tests including palpation of symphysis pubis and modified Trendelenburg was carried out. For patients with pain in SI joint, special tests including P4/thigh thrust test, and Patrick's Faber test were carried out. Other parts of questionnaire consist of pain drawing, VAS for intensity of pain, OSWESTRY disability index and WHO quality of life questionnaires. Participants will be allocated in 3 groups, including 2 interventions and 1 control, through randomization and will be prescribed exercise plus educational pamphlet, abdomino lumbo pelvic belt with educational pamphlet and educational pamphlet alone respectively for 6 weeks. The questionnaire will be completed at the beginning, 3 and 6 weeks after interventions. Primary outcome of this study is improvement in back pain during pregnancy. The purpose of this study is to evaluate the effectiveness of these treatments in improvement of low back pain, disability and quality of life in pregnant women.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812113470N1**

Registration date: **2010-06-05, 1389/03/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-06-05, 1389/03/15

Registrant information

Name

Maryam Abolhasani

Name of organization / entity

Tehran University of Medical Sciences and Health Services , Sports Medicine Research Center.

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences and Health Services.

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2010-10-23, 1389/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between two types of treatment in pelvic girdle pain in pregnancy: Abdomino lumbo pelvic belt and exercise therapy.

Public title
Comparison between effects of abdomino lumbo pelvic belt and exercise therapy in low back pain in pregnancy.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1- Healthy pregnant women with pain in lumbar region. 2- Pregnancy age: 20-32 weeks of pregnancy. 3- The consent will be received from all participants. 4- Mono fetus pregnancy. 5- Pelvic girdle pain had been diagnosed with history, physical examination and specific tests. 6- Contraindications of exercise in pregnancy should not be existed in participants such as: vaginal bleeding, preeclampsia, IURG, placenta previa, preterm labor, cervix insufficiency, rupture of membrane in recent pregnancy. 7- Systemic diseases should not be existed in participants such as: restrictive lung diseases, heart diseases. Exclusion criteria: 1- If contraindications of exercise in pregnancy happened during study. 2- If participants don't refer after 3 and 6 weeks of intervention. 3- If participants don't use belt and exercise regularly.

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description

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

Research Deputy of Tehran University of Medical Sciences and Health Services

Street address

Keshavarz Blvd., GHods Avenue crossing.
City
Tehran
Postal code
Approval date
empty
Ethics committee reference number
1387-02-53-7126

Health conditions studied

1

Description of health condition studied

low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Back pain

Timepoint

3 and 6 weeks after interventions

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Quality of life

Timepoint

3 and 6 weeks after interventions

Method of measurement

WHO quality of life questionnaire

2

Description

Patient's ability in implementation of daily activities

Timepoint

3 and 6 weeks after interventions

Method of measurement

OSWESTRY disability questionnaire

Intervention groups

1

Description

Prescription of an abdomino lumbo pelvic belt in group1 of trial with educational pamphlete consists of usual care in prevention and treatment of low back pain in pregnancy for 6 weeks.

Category

Treatment - Other

2

Description

Exercise prescription in group 2 of trial consist of stretching and strenghtening of abomen, lumbar and pelvic muscles and core stability exercises with one booklet consists of guidelines for these exercises and educational pamphlete consists of usual care in treatment and prevention of low back pain in pregnancy for 6 weeks.

Category

Rehabilitation

3

Description

An educational pamphlete in control group consists of usual care for treatment and prevention of low back pain in pregnancy for 6 weeks.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini Hospital..

Full name of responsible person

Maryam Abolhasani

Street address

The end of Keshavarz BLVD., Imam Khomeini Hospital.

City

Tehran

2

Recruitment center

Name of recruitment center

Sports medicine research center.

Full name of responsible person

Maryam abolhasani.

Street address

No 7, Jalal Al Ahmad Highway, opposite of Shariatee Hospital's clinics, Sports medicine research center

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tehran University of Medical Sciences and Health Services

Full name of responsible person

Dr. Ramin Kordi.

Street address

No 7, Jalal Al Ahmad Highway, opposite of Shariatei Hospital's clinics, Sports medicine research center

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Deputy of Tehran University of Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Sports medicine research center.

Full name of responsible person

Maryam Abolhasani

Position

Resident of sports medicine.

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Assistant professor of Tehran University of Medical Sciences and Health Services. MD. PHD of sports

Full name of responsible person

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Position

Sports medicine specialist.

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty