Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 regularely.
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
Prescribtion 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 prescribtion 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.
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Tehran

2

Recruitment center
Name of recruitment center
Sports medicine research center.
Full name of responsible person
Maryam abolhasani.
Street address
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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
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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
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
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Person responsible for scientific inquiries

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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