

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigation the effect of stabilization exercises on pain, disability and pelvic floor muscles activity in patients with postpartum lumbopelvic pain: A Randomized Clinical Trial

Protocol summary

Summary

Objectives: Investigation of the effect of stabilization exercises on pain, disability and pelvic floor muscles activity in patients with postpartum lumbopelvic pain

Design: In this randomized controlled trial (phase 2), 36 women with postpartum lumbopelvic pain were selected through nonprobability simple sampling and were assigned randomly to 2 groups by using consecutive assignment, Stabilization exercises(18 subjects) and Control group(18 subjects). **Setting:** This randomized clinical trial was performed in Zahedan University of Medical Sciences, from September 2015 to February 2016. **Inclusion criteria:** age more than 18 years old; pain located between costal margin to gluteal fold with or without radiation to lower limbs; onset of pain during pregnancy or after delivery; history of delivery at least 3 months ago. **Exclusion criteria:** history of fracture; neoplasm; intervertebral disk pathology or radiculopathy; spondylolysis or spondylolysthesis; ongoing pregnancy; treatment with specific stabilisation exercise during previous 3 months. **Sample size:** 36 subjects(18 person in control group and 18 person in training group). **Intervention group:** physical therapy with specific stabilization exercises in training group for 6 weeks (18 sessions every other day). **control group:** physical therapy without stabilization exercises in control group for 6 weeks(18 sessions every other day). **Outcomes:** Variables were include of pain, disability, pelvic floor muscle activity that measured one day before of the intervention and one day after the intervention. the pain intensity is measured using Visual Analog Scale(VAS) the disability is measured using Oswestry Disability Index(ODI) The pelvic floor muscle activity is measured using Transabdominal approach of ultrasound imaging. in this approach bladder wall displacement was measured as a function of the pelvic floor muscles at rest and during maximal contraction.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016053128186N1**

Registration date: **2016-08-18, 1395/05/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-18, 1395/05/28

Registrant information

Name

Mohammad Hosseinifar

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zahedan University of Medical Sciences research, Deputy of Research.

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-02-18, 1394/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation the effect of stabilization exercises on pain, disability and pelvic floor muscles activity in patients with postpartum lumbopelvic pain: A Randomized Clinical Trial

Public title
The effect of stabilization exercises in postpartum lumbopelvic pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: age more than 18 years old; pain located between costal margin to gluteal fold with or without radiation to lower limbs; onset of pain during pregnancy or after delivery; history of delivery at least 3 months ago. Exclusion criteria: known chronic rheumatologic or Orthopedic disorders; systemic locomotor disease; history of fracture; neoplasm; intervertebral disk pathology or radiculopathy; spondylolysis or spondylololsthesis; contraindication of exercises; heart disease; diabetes; thrombophlebitis; uncontrolled epilepsy; ongoing pregnancy; treatment with specific stabilisation exercise during previous 3 months.

Age
From **18 years** old to **58 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this clinical trial (phase 2) patients by using consecutive assignment were assigned into two groups,Stabilization exercise(18 subjects) and Control group(18 subjects).

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences
Street address
Deputy of Research, Zahedan University of Medical Sciences, Jannat Blvd., Dr. Hesabi Sq.
City
Zahedan
Postal code
9816743463
Approval date
2015-10-11, 1394/07/19
Ethics committee reference number
IR.ZAUMS.REC1394.280

Health conditions studied

1

Description of health condition studied
Postpartum Low Back Pain
ICD-10 code
M54.9
ICD-10 code description
Dorsalgia, unspecified

Primary outcomes

1

Description
pain
Timepoint
Before and after the period of the interventions
Method of measurement
Visual Analog Scale(VAS) questionnaire

2

Description
Disability
Timepoint
Before and after the period of the interventions
Method of measurement
Oswestru Disability Index(ODI) questionnaire

3

Description
Pelvic Floor Muscle activity
Timepoint
Before and after the period of the interventions
Method of measurement
transabdominal approach of Ultrasound imaging

Secondary outcomes

empty

Intervention groups

1

Description

control group:18 sessions during 6 consecutive weeks, three times per week, per session including: Twenty minutes for receiving hot pack and TENS

Category

Rehabilitation

2

Description

Stabilization exercise group: 18 sessions during 6 consecutive weeks, three times per week, 30 or 40 minutes per session including: Twenty minutes for receiving hot pack and TENS and 10 or 20 minutes for training the exercises in 7 level : 1.Train the specific contraction of the deep abdominal muscles, multifidus and pelvic floor muscles(PFM). 2.Train the specific contraction of deep abdominal muscles with coactivation of multifidus and PFM in supine, prone, sitting, standing and quadruped position. 3. Segmental control exercises in close kinematic chain. 4. Segmental control exercises in open kinematic chain with limb loading, emphasis on abdominal muscles. 5. Segmental control exercises in open kinematic chain with limb loading, emphasis on back extensor muscles. 6. Progress exercises to functional task. 7. Coactivation of abdominal and multifidus muscles with limb loading in aerobic tasks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Razmjo Moghadam Physiotherapy Clinic

Full name of responsible person

Dr.Mohammad Hosseinifar

Street address

Dept. of Physiotherapy, School of Rehabilitation Sciences, Razmejo Moghadam Laboratory, Ayatoallah Kafami St.

City

zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Zahedan University of Medical Sciences

Full name of responsible person

Dr. Hoshang rafigdost

Street address

Deputy of Research, Zahedan University of Medical

Sciences, Jannat Blvd., Dr. Hesabi Sq.

City

zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Zahedan University of Medical Sciences

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

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hosseinifar

Position

Ph.D in Physiotherapy

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