Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A comparative study of stabilization exercise focusing pelvic floor muscles training and routine physiotherapy on pain, disability and muscles thickness in females with low back pain following pregnancy

Protocol summary

Summary

Objective: evaluation the effect of stabilization exercise with an emphasis on deep muscles of the pelvic floor and deep abdominal muscles in compare with routine physiotherapy on pain, disability and thickness of deep abdominal muscle and pelvic floor in women with back ache of pregnancy. Study design: randomly, without placebo control, single central. The study population: 60 persons of women with back ache after pregnancy period referred to Neuromuscular Rehabilitation research center for physiotherapy. Inclusion criteria: age between 20 to 40 years; natural childbirth; first delivery; pain from T12 area to gluteus muscles; persons with L5-S1 terminal or lateral pain in gluteal area. Exclusion criteria: acute inflammation or infectious disease, cerebral disorder and back ache of internal organ disorders, chronic back ache more than 3 months; history of fracture and neoplasms or spine, pelvic or femoral surgery; new pregnancy Sample size, intervention, intervention time, outcome of study: sample size for this study is 60 persons in intervention (stabilization exercise) and control (routine exercise) group. Intervention group: 30 persons in intervention group, 8 weeks exercise therapy with 3 sessions per week (each session 3 sets of 10 to 12 times) is performed. Muscle contraction will keep for 6 to 8 seconds then rest for a few seconds and then repeat. Each of stability exercises are doing for strengthen abdominal muscles. Control group: 30 persons in control group, only receive routine exercise and they are only to compare the results with the intervention group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060125732N18**
Registration date: **2017-06-11, 1396/03/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-11, 1396/03/21

Registrant information

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-08-21, 1396/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of stabilization exercise focusing pelvic floor muscles training and routine physiotherapy on pain, disability and muscles thickness in females with

low back pain following pregnancy

Public title
A comparative study of stabilization exercise focusing pelvic floor muscles training and routine physiotherapy on pain, disability and muscles thickness in females with low back pain following pregnancy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: age between 20 to 40 years; pain from T12 area to gluteus muscles with or without pain to knees; People who have 2 or more than 2 pelvic pain are positive in stimulation test; pain during pregnancy or 3 weeks after delivery; persons with L5-S1 terminal or lateral pain in gluteal area; natural childbirth; first delivery. Exclusion criteria: acute inflammation or infectious disease, cerebral disorder and backache of internal organ disorders; chronic back ache more than 3 months and pain to blew the knees, people who have a locomotor disorders, verified and identified the spinal cord problems in last 2 months; history of fracture and neoplasms or spine, pelvic or femoral surgery; treatment with stabilization exercises during the previous 3 months; new pregnancy.
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Ethics Committee, Deputy of research and technology, Semnan University of Medical Sciences
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan
City
Semnan
Postal code
3514799442
Approval date
2017-05-21, 1396/02/31
Ethics committee reference number
IR.SEMUMS.REC.1396.-----

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
The thickness of the abdominal muscles
Timepoint
Before and after the intervention
Method of measurement
Ultrasonography HS-2100V

2

Description
Pain intensity
Timepoint
Before and after intervention
Method of measurement
VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30 persons in intervention group, 8 weeks exercise therapy with 3 sessions per week (each session 3 sets of 10 to 12 times) is performed. Muscle contraction will keep for 6 to 8 seconds then rest for a few seconds and then repeat. Each of stability exercises are doing for strengthen abdominal muscles.
Category
Rehabilitation

2

Description
Control group: 30 persons in control group, only receive

routine exercise and they are only to compare the results with the intervention group.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Neuromuscular Rehabilitation Research Center
Full name of responsible person
Fatemeh Ehsani
Street address
Blvd Qods, Semnan
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences, Deputy of Research and Technology
Full name of responsible person
Mohammadreza Asgari
Street address
Semnan University of Medical Sciences, Deputy of Research and Technology, Basij Blvd, Semnan
City
Semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan University of Medical Sciences, Deputy of Research and Technology
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
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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