

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Registration timing: **registered_while_recruiting**

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.

Last update:

Update count: **0**

Registration date

2017-06-11, 1396/03/21

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

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

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060125732N18**

Registration date: **2017-06-11, 1396/03/21**

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

Semnan

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****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Fatemeh Ehsani

Position

physiotherapist

Other areas of specialty/work**Street address**

Semnan University of Medical Sciences, Blvd Basij, Semnan

City

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Fax

+98 23 3344 8999

Email

are20935@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Semnan University of Medical Sciences

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Fatemeh Ehsani

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Semnan University of Medical Sciences, Blvd Basij, Semnan

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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are20935@gmail.com

Web page address

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