

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effects of Pelvic Clock vs Pelvic Tilt Exercises on pregnant women with low back pain during their third trimester

Protocol summary

Study aim

To compare the effects of pelvic floor exercises and pelvic tilt exercises on low back pain during third trimester of pregnancy

Design

A randomized open-label parallel control group clinical trial.

Settings and conduct

Patients will be recruited according to the inclusion criteria of study, from Mola Bakhsh Hospital Sargodha and District Headquarter Hospital Sargodha. After this initial assessment will be performed and patients will be randomized in two groups to receive their respective treatment. Outcomes will be assessed before and after completion of treatment.

Participants/Inclusion and exclusion criteria

INCLUSION CRITERIA: • Age limit 25 to 35 • Pregnant women with low back pain in 3rd trimester. EXCLUSION CRITERIA: • Systemic illness • Traumatic injury • Previous surgery.

Intervention groups

Intervention Group 1: Hot pack will be applied for 10 minutes and then pelvic tilt exercises will be performed for 15 minutes for the treatment of low back pain. 5 sessions/week will be given for 4 weeks. Intervention Group 2: Hot pack will be applied for 10 minutes and then pelvic clock exercises will be performed for 15 minutes. 5 sessions/week will be given for 4 weeks. Treatment time of each session be approximately 25 minutes.

Main outcome variables

Visual analogue scale (VAS), Oswestry disability index (ODI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210730052018N1**

Registration date: **2021-09-09, 1400/06/18**

Registration timing: **retrospective**

Last update: **2021-09-09, 1400/06/18**

Update count: **0**

Registration date

2021-09-09, 1400/06/18

Registrant information

Name

Bushra Mushtaq

Name of organization / entity

Government college university Faisalabad

Country

Pakistan

Phone

+92 48 3252717

Email address

bushaamushtaq213@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-04, 1400/05/13

Expected recruitment end date

2021-09-04, 1400/06/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Pelvic Clock vs Pelvic Tilt Exercises on pregnant women with low back pain during their third trimester

Public title

Effects of Pelvic Clock vs Pelvic Tilt Exercises on pregnant women with low back pain during their third trimester

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age limit 25 to 35 Pregnant women with low back pain in 3rd trimester

Exclusion criteria:

Any systemic illness Gestational diabetes Urinary tract infection Multiple pregnancy Complication during pregnancy First and second trimester Traumatic injury Any previous surgery

Age

From **25 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Written informed consent will be taken. After enrollment into study, patients will be allocated either to Group 1 or Group 2 by lottery method. No. of chits will be equal to total sample size, odd no. will be allocated to Group 1 and even no. will be allocated to Group 2. Each patient will be requested to draw a chit from the box and after that patient will be recruited into either Group 1 or Group 2.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Non-probability purposive sampling will be used to recruit the individual for the study and then randomization will be done by lottery method to allocate the individual to two interventional groups. Sealed envelopes will be used for allocation concealment.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Sargodha Institute of Health Sciences (SIHS),
Research Ethical Committee (REC)

Street address

117-C, Zafar Ullah Road, Satellite Town, Sargodha.

City

Sargodha

Postal code

40100

Approval date

2021-07-17, 1400/04/26

Ethics committee reference number

SIHS/21/157

Health conditions studied**1****Description of health condition studied**

Low back pain is leading health problem in lumbosacral region. It is defined by muscle tension, or stiffness localized below the costal margin and above the inferior gluteal folds. The symptoms of low back pain occurs in people of all ages .The low back pain symptoms may be short lasting but frequent occurrence is common , the acute episode lasts from few days to four weeks while sub-acute phase of low back pain lasts for four to twelve weeks and chronic low back pain persists from months and years. It is a composite condition with several contributing factors involving psychological factors, social factors and biophysical factors

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes**1****Description**

pain

Timepoint

before treatment, after treatment (4th week)

Method of measurement

Visual analogue scale (VAS)

2**Description**

Functional performance

Timepoint

before treatment, after treatment (4th week)

Method of measurement

Oswestry Disability Index (ODI)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: After taking baseline measures group A patients will receive hot pack for 10 minutes and pelvic tilt exercise for 15 minutes. 5 sessions/ week will be given for 4 weeks

Category

Other

2

Description

Intervention group 2: After taking baseline measures group B patients will receive hot pack for 10 minutes and pelvic clock exercise for 15 minutes. 5 sessions/week will be given for 4 weeks. Treatment time of each session will be approximately 25 minutes

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mola Bakhsh Hospital Sargodha

Full name of responsible person

Bushra Mushtaq

Street address

Sulemanpura, Sargodha, Punjab

City

Sargodha

Postal code

40100

Phone

+92 48 3726938

Email

bushaamushtaq213@gmail.com

Web page address

<https://www.medicall.com.pk/hospital?id=mola-bakhsh-hospital-72287>

2

Recruitment center

Name of recruitment center

District Headquarter Hospital Sargodha.

Full name of responsible person

Bushra Mushtaq

Street address

Thana Rd, Bhalwal, Sargodha, Punjab

City

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bushaamushtaq213@gmail.com

Web page address

<https://punjab.gov.pk/node/859>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mola Bakhsh hospital Sargodha

Full name of responsible person

Bushra Mushtaq

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Sargodha, Punjab, Pakistan

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Web page address

<https://www.medicall.com.pk/hospital?id=mola-bakhsh-hospital-72287>

Grant name

Grant code / Reference number

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

No

Title of funding source

Mola Bakhsh Hospital, Sargodha

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Sargodha Institute of Health Sciences

Full name of responsible person

Bushra Mustaq

Position

Senior lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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bushaamushtaq213@gmail.com
Web page address
<https://www.medicall.com.pk/hospital?id=mola-bakhs-h-hospital-72287>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further decision and information decided yet

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available