

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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.medical.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**

Sargodha

**Postal code**

181206

**Phone**

+92 48 6642700

**Email**

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

**Street address**

Sargodha, Punjab, Pakistan

**City**

Sargodha

**Postal code**

40100

**Phone**

+92 48 3726938

**Email**

bushaamushtaq213@gmail.com

**Web page address**

<https://www.medical.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

**Street address**

House no 1428 Mohallah Qazian Wala khushab.

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**Web page address**

<https://www.medical.com.pk/hospital?id=mola-bakhs-h-hospital-72287>

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Sargodha Institute of Health Sciences

**Full name of responsible person**

Bushra Mushtaq

**Position**

Senior lecturer

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Sargodha Institute of Health Sciences

**Full name of responsible person**

Bushra Mushtaq

**Position**

Senior lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

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<https://www.medical.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