

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Comparison of effect of isometric exercises and pelvic tilt on the lumbar and pelvic pain in secondary trimester in primary gravida women

#### Protocol summary

The severity of back pain; The severity of pelvic pain;  
Duration of back pain; Duration of pelvic pain

#### Study aim

Comparison of effect of isometric exercises and pelvic tilt on the lumbar and pelvic pain in secondary trimester of pregnancy

#### Design

Clinical trial with a control group, with parallel, randomized groups with a sample size of 120 people

#### Settings and conduct

The researcher started to sample qualified people by referring to clinics in Bushehr during the study period. Then Each of the two test groups receive basic training individually in theory and practice by the trained individual. In the control group, only routine pregnancy cares is done. At the beginning of the study, Week 4 and Eighth Week, extent and severity of back and hip pain are measured.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Primary gravida women, Age 18-35, 16-28 weeks of pregnancy, Visual Analog Scale(VAS) score of 20mm-70mm, Normal Body Mass Index(BMI), Not having a history of back pain before pregnancy, Not having a practice ban during pregnancy, Having reading and writing skills

#### Intervention groups

Intervention group 1: Isometric exercises are performed in the supine position. Over the course of eight weeks, it is done five times per week and it involves the isometric contraction of the abdominal transverse muscles, the gluteal and the bottom of the pelvic, that each contraction is kept 5 seconds and 5 seconds rest with iteration 10 times. Intervention group 2: The tilt exercise is performed in the supine position. While the legs extend outwards and stomach muscles and lower pelvis and buttock are contract, they lift the joint from the ground. they hold the position for five seconds and then released. The exercises are performed twice a day and 5 days a week for eight weeks. Control group: In the control group, only routine pregnancy cares is done.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190410043227N1**

Registration date: **2019-08-24, 1398/06/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-08-24, 1398/06/02**

Update count: **0**

##### Registration date

2019-08-24, 1398/06/02

##### Registrant information

##### Name

Sara Jomhourian angali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 77 3367 2979

##### Email address

s.jomhourian@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-09, 1398/05/18

##### Expected recruitment end date

2019-10-11, 1398/07/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Comparison of effect of isometric exercises and pelvic tilt on the lumbar and pelvic pain in secondary trimester in primary gravida women

## Public title

Comparison of effect of isometric exercises and pelvic tilt on the lumbar and pelvic pain in primary gravida women

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Primary gravida women Age 18-35 16-28 weeks of pregnancy Visual Analog Scale(VAS) score of 20mm-70mm Normal Body Mass Index(BMI) Not having a history of back pain before pregnancy Not having a practice ban during pregnancy Having reading and writing skills Satisfaction and willingness to participate in the study

### Exclusion criteria:

## Age

From **18 years** old to **35 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Permuted block randomization with a block size of 3 is used. Different permutations with the following sequence assigned to 1-6 include A=STUDY1, B=STUDY2, C=CONTROL, 1.ABC, 2.ACB, 3.BAC, 4.BCA, 5.CAB and 6.CBA. The numbers are now extracted from a table of random numbers in a way that 55 blocks of size 3 are selected one at a time and depending on the corresponding randomly-selected number between 1 and 6. Zero, seven, eight and nine are ignored if selected, and the procedure continues until the list is completed for the whole sample.

## 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 of Shiraz University of Medical Sciences

##### Street address

Central building of Shiraz University of Medical Sciences, Zand Ave.,

##### City

Shiraz

##### Province

Fars

##### Postal code

71936-13119

#### Approval date

2019-03-05, 1397/12/14

#### Ethics committee reference number

IR.SUMS.REC.1398.208

## Health conditions studied

### 1

#### Description of health condition studied

Back pain

#### ICD-10 code

M54.5

#### ICD-10 code description

low back pain

### 2

#### Description of health condition studied

Pelvic pain

#### ICD-10 code

R10.3

#### ICD-10 code description

Pain localized to other parts of lower abdomen

## Primary outcomes

### 1

#### Description

Visual Analogue Scale score of back pain

#### Timepoint

Before intervention, 4 & 8 weeks later

#### Method of measurement

Visual Analogue Scale questionnaire

### 2

#### Description

Pelvic pain severity

#### Timepoint

Before intervention, 4 & 8 weeks later

#### Method of measurement

Active Straight Leg Raise(ASLR) test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the first group, isometric exercises are performed in the supine position. Over the course of eight weeks, is done five times a week. It is done five times per week and it involves the isometric contraction of the abdominal transverse muscles, the gluteal and the bottom of the pelvis, that each contraction is kept 5 seconds and 5 seconds rest with iteration 10 times.

#### Category

Treatment - Other

### 2

#### Description

In the second group, the tilt exercise is performed in the supine position with the bent over of the knees and hip on the ground. While the legs extend outwards and stomach muscles and lower pelvis and buttock are contract, they lift the joint from the ground. With a deep breath, they hold the position for five seconds and then released. Then they place their buttock on the ground and relax their muscles for 5 seconds. The exercises are performed within five days of the week for eight weeks with a repeat of 2 times a day.

#### Category

Treatment - Other

### 3

#### Description

In the control group, only routine pregnancy cares is done and Do not see any training.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Health center of Bushehr city

##### Full name of responsible person

Hasan Fakhraei

##### Street address

Health center of Bushehr city, Dashtestan Alley,  
Daneshamooz Ave

##### City

Bushehr

##### Province

Boushehr

##### Postal code

7516965593

##### Phone

+98 77 3335 0038

#### Fax

#### Email

bu\_hc\_2008@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Yuones Ghasemi

##### Street address

Central building of Shiraz University of Medical  
Sciences, Opposite the street of Palestine, Zand Ave.,

##### City

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##### Province

Fars

##### Postal code

۱۴۳۳۶۷۱۳۴۸

##### Phone

+98 71 3212 2430

##### Email

vrdep@sums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shiraz University of Medical Sciences

#### 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

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Sara Jomhour Angali

##### Position

Master student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Midwifery

##### Street address

Faculty of nursing and midwifery, Namazi Square,  
Zand Ave.,

##### City

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7193613119  
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## Person responsible for scientific inquiries

### Contact

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Shiraz University of Medical Sciences  
**Full name of responsible person**  
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Midwifery  
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## Person responsible for updating data

### Contact

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Shiraz University of Medical Sciences  
**Full name of responsible person**

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**Position**  
Master student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
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**Street address**  
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7193613119  
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s.jomhuri@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

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

### 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