

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Assesment of spinal thoracolumbosacral manipulation's effect on pain in women with primary dysmenorrhea in emam reza hospital, Tehran in 1395

#### Protocol summary

##### Study aim

- 1.determine pain intensity in lower abdomen according to VAS in case and control groups before and after manipulation in first, second and third cycles
- 2.determine pain intensity in pelvicaccording to VAS in case and control groups before and after manipulation in first, second and third cycles
- 3.determine pain intensity in low back according to VAS in case and control groups before and after manipulation in first, second and third cycles
- 4.determine NSAIDs tablet consumption in case and control groups before and after manipulation in first, second and third cycles
5. determine bleeding in case and control groups before and after manipulation in first, second and third cycles

##### Design

Two arm parallel group randomised trial with blinded outcome assessment

##### Settings and conduct

we explain study planning for all patients, based on patient satisfaction, she enters one of two groups. Patients are examined by a researcher number two who is blind to the grouping of patients, and measure spinal range of motion in Emam reza hospital. Patients in intervention group have been manipulated in lumbosacral region and thoracolumbar junction at 15,21 and 28 days after menstruation onset. stretching and strengthening exercise are taught to both groups that they start at 15th cycle and stop with menstruation.all patient can take diclofenac 50 mg.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: age 18-45 years, regular menstrual cycles , moderate to severe pain , dysmenorrhea symptom during 1 year ago , VAS more than 5 for pelvic pain , low back pain ,no manipulation 2 month before

##### Intervention groups

Intervention group:manipulate lumbosacral and thoracolumbar junction +6 type strengthening and

stretching abdominal exercises Control group:the same intervention group exercise

##### Main outcome variables

pain (VAS) in low back , pelvic , lower abdomen  
determine bleeding , diclofenac intake

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180113038348N1**  
Registration date: **2018-04-24, 1397/02/04**  
Registration timing: **retrospective**

Last update: **2018-04-24, 1397/02/04**

Update count: **0**

##### Registration date

2018-04-24, 1397/02/04

##### Registrant information

##### Name

Hoda Jazayeri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8827 2477

##### Email address

hoda.jazayeri@ajaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-11-20, 1395/08/30

##### Expected recruitment end date

2018-04-19, 1397/01/30

**Actual recruitment start date**

2016-11-20, 1395/08/30

**Actual recruitment end date**

2018-03-10, 1396/12/19

**Trial completion date**

empty

**Scientific title**

Assesment of spinal thoracolumbosacral manipulation's effect on pain in women with primary dysmenorrhea in imam reza hospital, Tehran in 1395

**Public title**

Assesment of spinal thoracolumbosacral manipulation's effect on pain in women with primary dysmenorrhea

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

regular menstrual cycles moderate to severe menstrual pain no manipulation 2 month before arrival in study  
Minimum age 18 and maximum age 45 year old

**Exclusion criteria:**

use OCP tablet or IUD pelvic abnormality endometriosis PCOS ,fibroid , PID , cancer spinal fracture

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **34**

Actual sample size reached: **32**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

randomization is done through randomized number table

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Evaluator is blinded toward the group of patients

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee**

**Name of ethics committee**

ethics committee of AJA university of medical science

**Street address**

Etemad zade st,west fatemi st

**City**

Tehran

**Province**

Tehran

**Postal code**

88028350

**Approval date**

2016-10-02, 1395/07/11

**Ethics committee reference number**

IR.AJAUMS.REC.1395.20

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

dysmenorhea

**ICD-10 code**

N94.4

**ICD-10 code description**

Primary dysmenorrhea

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

pain score

**Timepoint**

15th first menstruation and 15th second menstruation

**Method of measurement**

VAS

**Secondary outcomes****1****Description**

lumbar junction ROM

**Timepoint**

15th first menstruation and 15th second menstruation

**Method of measurement**

measured by Zebris

**2****Description**

thoracolumbar junction

**Timepoint**

15th first and second menstruation cycles

**Method of measurement**

measured by goniometer

**3****Description**

number of diclofenac 50 mg that was used

**Timepoint**

first and second menstruation cycles

**Method of measurement**

number

**4****Description**

volume of bleeding

**Timepoint**

first and second cycles

**Method of measurement**

number of used pad

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

Intervention group: Performing manipulation on days 15, 21 and 28 of the patient's cycle simultaneously with strengthening and stretching exercises starting from 15 cycles and stop with menstruation on day 28

**Category**

Treatment - Other

**2****Description**

Control group: From the 15th cycle until the menstruation on day 28, they perform 6 strengthening and stretching exercises

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Emam Reza hospital

**Full name of responsible person**

Hoda jazayeri

**Street address**

Etemad zade st,West Fatemi st,Emam Reza hospital

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**Postal code**

9132616040

**Phone**

+98 21 8802 8350

**Email**

hoda.jazayeri@ajaums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Dr Kamran Azma

**Street address**

Etemad zade St,West Fatemi St,Emam Reza Hospital

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Artesh 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**

Artesh University of Medical Sciences

**Full name of responsible person**

Hoda Jazayeri

**Position**

Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant

**Latest degree**

Medical doctor

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## **Person responsible for updating data**

### **Contact**

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Artesh University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant

**Latest degree**

Medical doctor

### **Other areas of specialty/work**

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## **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