

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

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Etemad zade st,West Fatemi st,Emam Reza hospital

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

Artesh University of Medical Sciences

Full name of responsible person

Dr Kamran Azma

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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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inquiries

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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