Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect duloxetine versus amitriptyline on clinical outcomes of female with chronic pelvic pain syndrome: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of duloxetine versus amitriptyline on clinical outcomes of female with chronic pelvic pain syndrome

Design
This is a double-blind randomized clinical trial, phase III. The control group receives standard treatment. In this trial the eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct
This study will be performed in the Beheshti Hospital in Hamadan city on 48 eligible patients with chronic pelvic pain syndrome. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 50 years Chronic pelvic pain syndrome for more than 6 months Being literate Exclusion criteria: Pregnancy or breastfeeding Suffering from endometriosis, ovarian cyst, adenomyosis, fibroid or genital malignancy Gastrointestinal diseases including irritable bowel syndrome or inflammatory bowel disease History of previous hip surgery Genitourinary infection Cognitive or mental disorders Kidney and liver dysfunction History of alcohol and substance abuse

Intervention groups
Intervention group: Duloxetine tablets 30 mg daily for one week then 60 mg daily for 8 weeks Control group: Amitriptyline tablets 25 mg daily for one week then 50 mg daily for 8 weeks

Main outcome variables
Primary outcome: Improvement of clinical symptoms The rate of overall response to treatment Secondary outcome: Occurrence of side effects (nausea, vomiting)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N457**
Registration date: **2023-01-10, 1401/10/20**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-10, 1401/10/20**
Update count: **0**

Registration date
2023-01-10, 1401/10/20

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-05, 1401/10/15

Expected recruitment end date
2024-01-05, 1402/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect duloxetine versus amitriptyline on clinical

outcomes of female with chronic pelvic pain syndrome: a double-blind randomized clinical trial

Public title
Effect duloxetine versus amitriptyline on clinical outcomes of female with chronic pelvic pain syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 50 years Chronic pelvic pain syndrome for more than 6 months
Exclusion criteria:
Pregnancy or breastfeeding Suffering from endometriosis, ovarian cyst, adenomyosis, fibroid or genital malignancy Gastrointestinal diseases including irritable bowel syndrome or inflammatory bowel disease History of previous hip surgery Genitourinary infection Cognitive or mental disorders Kidney and liver dysfunction History of alcohol and substance abuse
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drugs will be given in coded envelopes. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
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Hamadan
Postal code
6517838695
Approval date
2022-10-23, 1401/08/01
Ethics committee reference number
IR.UMSHA.REC.1401.621

Health conditions studied

1

Description of health condition studied
Chronic pelvic pain syndrome
ICD-10 code
R10.2
ICD-10 code description
Pelvic and perineal pain

Primary outcomes

1

Description
Improvement of clinical symptoms (pain, difficulty in defecation)
Timepoint
Before the intervention and one and two months after that
Method of measurement
Using the National Institutes of Health Chronic Syndrome Symptom Index (NIH-CSSI)

2

Description
The rate of overall response to treatment
Timepoint
Two months after the intervention
Method of measurement
Using the Global Response Assessment (GRA) questionnaire

Secondary outcomes

1

Description
Occurrence of side effects (nausea, vomiting)
Timepoint
one and two months after intervention
Method of measurement
With history taking

Intervention groups

1

Description
Intervention group: Duloxetine tablets 30 mg daily for one week then 60 mg daily for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Amitriptyline tablets 25 mg daily for one week then 50 mg daily for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital in Hamadan city
Full name of responsible person
Rojan Ghaderzadeh
Street address
Beheshti Hospital, Eram Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Reza Shokoohi
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Rojan Ghaderzadeh
Position
Student of Pharmacy
Latest degree
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Pharmacologist

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Ph.D.

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Medical Pharmacy

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Person responsible for updating data

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Professor of Epidemiology

Latest degree
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Other areas of specialty/work
Epidemiology

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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