

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison between the effect of oral Pregabalin (75 mg) and Deuloxetin (30mg) with Amitryptilin) on decreasing chronic pelvic pain due to Endometriosis

Protocol summary

Summary

The aim of the current study was a comparison between the effect of oral Pregabalin (75 mg) and oral Deuloxetin (30mg) (with Amitryptilin) on decreasing of chronic pelvic pain due to Endometriosis at Alzzahra Hospital throught 2014 and 2015. Inclusion Criteria were: Known case of Endometriosis (according to the pathologic or radiologic measures); Pelvic pain more than 6 months; Age between 18-60 years old; preception and signing of the consent inform. Exclusion Criteria: Previous surgeries; Need to strong opioids; co-existing pelvic disorders; History of urinary tract infection; Pregnancy and breast feeding; Epilepsy; Hypertension; Hypersensitivity to drugs; MAOI consumption; Closed angle Glocoma; Renal Disorders; Juindice or hepatic disorders; Alcohol consumption; Hyponatremia; Body weight >285 Pound. Studied population were 100 cases with pelvic pain and no response to the previous treatments. Pain scores will be measured with (numerical rating scale) NRS between two groups. Then assessed 2weeks, 1month and 3 months later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042916325N2**

Registration date: **2015-06-26, 1394/04/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-06-26, 1394/04/05

Registrant information

Name

Katayoun Haryalchi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

Email address

haryalchi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research-Guilan University of Medical Sciences

Expected recruitment start date

2016-03-21, 1395/01/02

Expected recruitment end date

2018-03-22, 1397/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the effect of oral Pregabalin (75 mg) and Deuloxetin (30mg) with Amitryptilin) on decreasing chronic pelvic pain due to Endometriosis

Public title

An assessment about the effect of Pregabaline(75 mg) or Deuloxetin(30 mg) on pain relief in CPD due to Endometriosis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Known case of Endometriosis

according to pathology or radiology; Pelvic pain more than 6 month; Age between 18 and 60 years old; Comprehension and sign the consent inform. Exclusion Criteria: Previous surgery; Need to strong opioids; coexisting pelvic disorders; History of urinary tract infection, IBS, IBD, and cancer; Pregnancy and breast feeding; Psychiatric disorders (Minor and Major Depression, suicide, Bipolar disorders; Epilepsy; Hypertension; Hypersensitivity to drugs; MAOI consumption; Closed angle Glcoma; Renal Disorders; History of Juindice or hepatic disorders; Consumption of MAOI, SMRIs, SSRIs 2 weeks ago; Alcohol consumption; Hyponatremia; Weight gain > 285 Pound

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice Chancellor for Research-Guilan University of Medical Sciences

Street address

Vice Chancellor for Research-Guilan University of Medical Sciences , Gaz squire

City

Rasht

Postal code**Approval date**

2014-11-17, 1393/08/26

Ethics committee reference number

5930382802

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

Inflammatory disease of uterus, except cervix

ICD-10 code

N71.1

ICD-10 code description

Chronic inflammatory disease of uterus

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

Pain Score of Chronic pelvic pain due to Endometriosis

Timepoint

2 weeks, 1 month, and 3 months after receiving the first dose of drug

Method of measurement

Numerical Rating Scale (NRS)

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

Severity of Chronic pelvic pain due to Endometriosis

Timepoint

2 weeks, 1 month, and 3 months after receiving the first dose of drug

Method of measurement

With the question: How much do you experience pain relief after receiving treatment from our center? (0-100%)

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

Pregabalin 75 mg + Amitryptiline 10 mg

Category

Treatment - Drugs

2**Description**

Duloxetine 30 mg + Amitryptiline 10 mg

Category

Treatment - Drugs

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

Alzahra Hospital

Full name of responsible person

Dr. Roya Faraji

Street address**City**

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research-Guilan University of
Medical Sciences

Full name of responsible person

Dr. Abtin Hydarzadeh

Street address

Vice Chancellor for Research-Guilan University of
Medical Sciences, Gaz Square

City

Rasht

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

Yes

Title of funding source

Vice Chancellor for Research-Guilan University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin
Type of organization providing the funding

empty

Person responsible for general inquiries

Contact
Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Katayoun Haryalchi

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work
Street address

Alzahra Hospital, Namjoo Street

City

Rasht

Postal code
Phone

+98 133228724

Fax
Email

k_haryalchi@yahoo.com

Web page address

Person responsible for scientific

inquiries

Contact
Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Katayoun Haryalchi

Position

Assistant Professr of Anesthesiology

Other areas of specialty/work
Street address

Alzahra Hospital, Namjoo Street

City

Rasht

Postal code
Phone

+98 133228724

Fax
Email

k_haryalchi@yahoo.com

Web page address

Person responsible for updating data

Contact
Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Seyedeh Fatemeh Dalil Heirati

Position

B.Sc. Midwifery

Other areas of specialty/work
Street address

Alzahra Hospital, Namjoo Street

City

Rasht

Postal code
Phone

+98 13 3336 9224

Fax
Email

h_fertility@gums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty