Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparative effect of duloxetine and gabapentine on severity of pain and morphine consumption after total abdominal hysterectomy. A double blind clinical trail

Protocol summary

Summary

The aim of this study is to compare the effect of duloxetine and gabapentin on pain score after total abdominal hysterectomy. Inclusion criteria are being candidates for elective trans abdominal hysterectomy and age between 45 to 75. Exclusion criteria are history of sensitivity to medication study, patients that received analgesic 8 hours before surgery, history of asthma, history of hypertension and peripheral neuropathy .In a double blind randomized clinical trail 60 patient will be divided to two equals group(n=30) All the patients in control group receive preemptive gabapentin (600 mg)two hours before surgery. In case group all the patients receive preemptive duloxetine(60 mg) two hours before surgery. Pain score, need to analgesic drugs, patient satisfaction and time of discharge will be recorded and analyzed

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506301936N14**
Registration date: **2016-02-04, 1394/11/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-04, 1394/11/15

Registrant information

Name

Abdolreza Najafi Anaraki

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Sciences

Expected recruitment start date

2015-09-06, 1394/06/15

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effect of duloxetine and gabapentine on severity of pain and morphine consumption after total abdominal hysterectomy. A double blind clinical trail

Public title

The effect of duloxetine and gabapentine on pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all patients who are candidates for elective trans abdominal hysterectomy and age between 45 -75. Exclusion criteria: history of sensitivity to medication; patients that received analgesic 8 hours before surgery; history of asthma; history of hypertension and peripheral neuropathy.

Age

From **45 years** old to **75 years** old

Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
.
Secondary trial Id
.
Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee
Name of ethics committee
Busheher University of Medical Sciences
Street address
Siraf Avenue، Busheher
City
Busheher
Postal code
Approval date
2014-03-10, 1392/12/19
Ethics committee reference number
B-92-15-17

Health conditions studied

1

Description of health condition studied
Effect of duloxetine and gabapentine on post operative pain
ICD-10 code
M79.9
ICD-10 code description
Soft tissue disorder, unspecified

Primary outcomes

1

Description
post operative pain
Timepoint
First day, Second day
Method of measurement
visual

Secondary outcomes

1

Description
Patient Satisfication
Timepoint
Second day
Method of measurement
Question

Intervention groups

1

Description
In control group all patients receive 600 milligrams gabapebtin orally two hours before surgery
Category
Treatment - Drugs

2

Description
In case group all patients receive60 milligrams duloxetine orally two hours before surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye khalig fars Hospital
Full name of responsible person
Dr. Abdolreza Najafi Anaraki
Street address
Bushehr University of Medical Sciences -Siraf Street
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Bushehr

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bushehr University of Medical Sciences

Full name of responsible person
Dr Majid Asadi
Street address
Bushehr University of Medical Sciences، Siraf Street
City
Bushehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bushehr 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

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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