# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

05 Jul 2026

## Assessment of duloxetine effect on post-operative pain and recovery in patients who undergo abdominal hysterectomy under general anesthesia

## Protocol summary

**Study aim**

the main objective of this study is evaluating the effect of duloxetine on post-operative pain in abdominal hysterectomy.

**Design**

This is a randomised double blind clinical trial (phase 2-3) with blinded postoperative care and outcome assessment. The number of subjects is 70. The subjects are divided in 2 groups randomly using table of random numbers.

**Settings and conduct**

This study is performed on patients with hysterectomy surgery in Afzalipoor Hospital of Kerman. The person who perform the intervention is a nurse out of this study which gives the patients drug or placebo, so anesthesiologist, the patient and data collector and analyzer are unaware of used drug.

**Participants/Inclusion and exclusion criteria**

This study is a clinical trial on patients who are admitted in Afzalipoor Hospital of Kerman for hysterectomy which are given consent to participation. Exclusion criteria are long term usage of opioids a analgesics, taking steroids, age less than 18 and higher than 85, pregnancy, history of heart, hepatic and renal failure, uncontrolled hypertension, endocrine disorders, BMI more than 40.

**Intervention groups**

Patients in case group receive oral duloxedine 60 mg, 2 hours prior to surgery and patients in control group receive placebo. Anesthesia technique and medication in both groups are identical.

**Main outcome variables**

In all cases, vital signs, complications of duloxetine and amount of analgesics given to patient are checked prior to anesthesia; just after commence of surgery; at the time of giving isoflurane; during surgery and after operation and recovery time, every 15 minutes. The intensity of pain after anesthesia until discharge from recovery is determined and recorded. evaluation of pain in recovery is performed by means of Visual Analogue Scale (VAS). Patients discharged from recovery If they have scores of 9 or 10 according to aldrete scoring system. The amount of given analgesics in 24 hours is measured and overall patient satisfaction is assessed according to postoperative quality of recovery (QOR) score.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20120922010900N5**
Registration date: **2018-02-13, 1396/11/24**
Registration timing: **prospective**

Last update: **2018-02-13, 1396/11/24**
Update count: **0**

**Registration date**

2018-02-13, 1396/11/24

**Registrant information**

**Name**

Hosein Sattari

**Name of organization / entity**

kerman University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 34 1322 2250

**Email address**

sattari@kmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2018-02-20, 1396/12/01

**Expected recruitment end date**

2018-04-21, 1397/02/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Assessment of duloxetine effect on post-operative pain and recovery in patients who undergo abdominal hysterectomy under general anesthesia

**Public title**

Assessment of duloxetine effect on post-operative pain and recovery in patients who undergo abdominal hysterectomy under general anesthesia

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

All patients admitted to Afzalipoor Hospital for hysterectomy surgery ASA classification of I (without systemic disease) and II (with controlled systemic disease) informed consent of patient for participation

**Exclusion criteria:**

long term usage of opioids steroid thrapy age less than 18 and more than 85 year pregnancy heart, hepatic and renal failure uncontrolled hypertension endocrine diseases BMI greater than 40 heart rate less than 50 evidence of heart block in ECG presence of suizure, epilepsy and bipolar disorders surgery lasting more than 3 hours huge bleeding during surgery

**Age**

From **18 years** old to **85 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

the simple randomization is used to dividing the patients in 2 groups by means of table of random numbers.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

two hours before surgery, oral capsule of duloxetine is given to patients in case group and placebo (similar capsule containing starch) in control group. so, anesthesiologist, the patient and data collector are unaware of the kind of used drug.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Kerman University of Medical sciences

**Street address**

Jomhoori boulevard

**City**

Kerman

**Province**

Kerman

**Postal code**

7619813159

**Approval date**

2017-12-18, 1396/09/27

**Ethics committee reference number**

IR.KMU.REC.1396.1917

## Health conditions studied

### 1

**Description of health condition studied**

postoperative pain

**ICD-10 code**

G89.18

**ICD-10 code description**

Other acute postprocedural pain

## Primary outcomes

### 1

**Description**

postoperative pain

**Timepoint**

The level of pain is measured and documented every 15 minutes after patient reorientation, until discharge from recovery room.

**Method of measurement**

Visual Analogue Scale (VAS) is used for pain assessment

## Secondary outcomes

### 1

**Description**

Patient satisfaction

**Timepoint**

24 hours after surgery

**Method of measurement**
postoperative quality of recovery (QOR) score

**2**

**Description**
vital signs
**Timepoint**
every 15 minutes
**Method of measurement**
authomathic monitoring system

## Intervention groups

**1**

**Description**
Intervention group: two hours prior to surgery, patients in this group receive 60 mg oral capsule of duloxetine; brand name of Loxeta, made by Abidi pharmaceutical company.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: in this group, patients receive placebo.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Afzalipoor Hospital
**Full name of responsible person**
Hossein Sattari
**Street address**
Imam Khomeini Highway
**City**
Kerman
**Province**
Kerman
**Postal code**
7616913911
**Phone**
+98 34 1322 2250
**Email**
sattari@kmu.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kerman University of Medical Sciences
**Full name of responsible person**
Fatemeh Hassani
**Street address**
Tahmasbabad Square, Ebnesina Street
**City**
Kerman
**Province**
Kerman
**Postal code**
7619813159
**Phone**
+98 34 3223 5011
**Email**
f_hassani@kmu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Kerman 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**
Kerman University of Medical Sciences
**Full name of responsible person**
Fariba Mansoorinassab
**Position**
assistant of anesthesiology
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Anesthesiology
**Street address**
Afzalipoor Hospital, Zendan Square
**City**
Kerman
**Province**
Kerman
**Postal code**
7616913911
**Phone**
+98 34 3223 5011
**Email**
javakrd34@gmail.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Kerman University of Medical Sciences
**Full name of responsible person**
Hosein Sattari
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
**Street address**
Afzalipoor Hospital, Imamkhomeiny Highway
**City**
Kerman
**Province**
Kerman
**Postal code**
7616913911
**Phone**
+98 34 1322 2250
**Fax**
+98 34 1322 2763
**Email**
sattari@kmu.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Kerman University of Medical Sciences
**Full name of responsible person**
Fariba Mansoorinassab
**Position**
assistant of anesthesia
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Anesthesiology
**Street address**
Afzalipoor Hospital
**City**
Kerman
**Province**
Kerman
**Postal code**
7616913911
**Phone**
+98 34 1322 2250
**Fax**
**Email**
javakrd34@gmail.com
**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
postoperative pain patient satisfaction of recovery
**When the data will become available and for how long**
data will be available just after publication in journal.
**To whom data/document is available**
data will be available for people working in academic institutions.
**Under which criteria data/document could be used**
they can repeat statistical analysis.
**From where data/document is obtainable**
contact via email address of responsible person
**What processes are involved for a request to access data/document**
after confirming identity of requested person.
**Comments**