Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the analgesic effects of duloxetine in burn patients

Protocol summary

Summary

Objectives: Evaluation of the analgesic effects of duloxetine in burn patients Design: This study is a randomized open label clinical trial. Forty two patients from 1 center will be entered to the study. Patients will be randomly assigned to the intervention or control group based on simple block randomization. Setting: Patients will receive a 60 mg capsule of duloxetine per day in the intervention group. In the control group patients will receive no treatment. The patients will remain in the study for 3 weeks or for entire time of the hospitalization (which is shorter than the other) Participants: Patients who require hospitalization for at least 1 week will be recruited. Patients with hepatic failure, bipolar mood disorder and creatinine clearance less than 30 ml per minute and who are receiving potent inhibitors of cytochrome P450 (CYP) 2D6 and CYP1A2, will be excluded. Main outcome measures: Primary outcome variables: The severity and quality of the pain. These variables will be evaluated using visual analog scale and neuropathic pain scale. Secondary outcome variables: Dose of the other analgesic drugs that patients will receive during the study and adverse effects. Adverse effects will be recorded based on the patients' reports.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051422637N4**
Registration date: **2017-05-31, 1396/03/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-31, 1396/03/10

Registrant information

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Naemeh Nikvarz
Name of organization / entity
Kerman University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source
Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2017-01-30, 1395/11/11

Expected recruitment end date

2017-12-02, 1396/09/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the analgesic effects of duloxetine in burn patients

Public title

Evaluation of the analgesic effects of duloxetine in burn patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Burn patients requiring hospitalization for at least one week Exclusion criteria: Bipolar mood disorder; consuming monoamine oxidase inhibitor drugs, three cyclic antidepressant drugs, tramadol, buspirone, triptan drugs, lithium, ondansetron, potent inhibitors of

cytochrome P450 (CYP450) 2D6 and CYP450 1A2; creatinine clearance less than 30 ml per minute; hepatic failure; uncontrolled epilepsy; thrombocytopenia

Age
From **15 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not 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
Vice chancellor for research, Ebn-e-Sina Street

City
Kerman

Postal code

Approval date
2017-01-28, 1395/11/09

Ethics committee reference number
IR.KMU.REC.1395.680

Health conditions studied

1

Description of health condition studied
Burn

ICD-10 code
T20-T25

ICD-10 code description
Burns and corrosions of external body surface, specified by site

Primary outcomes

1

Description
Severity of pain

Timepoint
At baseline and every other day

Method of measurement
Visual Analog Scale

2

Description
Severity and quality of pain

Timepoint
At baseline and every other day

Method of measurement
Neuropathic Pain Scale

Secondary outcomes

1

Description
Dose of other analgesic drugs

Timepoint
At the end of the study

Method of measurement
Recording the dose of other analgesics

2

Description
Adverse effects

Timepoint
During the study

Method of measurement
Patient report

Intervention groups

1

Description
Intervention: a 60 mg oral capsule of duloxetine per day

Category
Treatment - Drugs

2

Description
Control: No treatment

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital
Full name of responsible person
Naemeh Nikvarz
Street address
Shafa Hospital, Kowsar Boulevard
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhti
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Vice chancellor for research, Ebn-e-sina Street
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Grant name
ندارد
Grant code / Reference number
95000039
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kerman 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