Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of memantine on opioid-induced hyperalgesia in opioid addict patients

Protocol summary

Study aim
Effectiveness of memantine on OIH in opioid addict patients
Design
Patients with opioid-induced hyperalgesia diagnose divided to 2 groups accidently by rand function of excel software and the first group treated with memantine and the other group with placebo. The patients do not know about intake of drug or placebo.
Settings and conduct
The patients put his hand in cold water with 1to5 celsius degree and after pain feeling and exit hand this time will be the first CPT. then we asses changes of this time and pain numbers after treatment with memantine. So analysis data with SPSS software will done.
Participants/Inclusion and exclusion criteria
Inclusion criteria: 1.opioid addict patients 2.from 18 to 60 years old 3.filling satisfaction form 4.no multi substance use in patients 5.no neurologic or nephrologic dysfunction 6.no unstable medical states 7.no Raynauds disease Exit criteria: 1.use other substance such as stimulants 2.memantine allergy 3.pregnancy
Intervention groups
We choose 34 opioid addict patients in beheshti hospital with intake of enough analgesics from NSAIDS with maximum allowed dose, that have complaints of pain and asses with Cold pressor test and grading by FACES pain numbres. patients with opioid-induced hyperalgesia diagnose divided to 2 groups and the first group treated with memantine and the other group with placebo.
Main outcome variables
severity of pain ranking by patients from 0 to 10 time of stay patients hand in cold water

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20211112053045N1**
Registration date: **2021-12-07, 1400/09/16**
Registration timing: **prospective**

Last update: **2021-12-07, 1400/09/16**
Update count: **0**
Registration date
2021-12-07, 1400/09/16

Registrant information
Name
Nafise sadat Haji seyed taghia
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 24 3354 4000
Email address
na_hst@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-12-22, 1400/10/01
Expected recruitment end date
2022-06-22, 1401/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of memantine on opioid-induced hyperalgesia in opioid addict patients

Public title
Effectiveness of memantine on opioid-induced

hyperalgesia in opioid addict patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

opioid addict patients from 18 to 60 years old filling satisfaction form no multi substance use in patients no neurologic or nephrologic dysfunction no unstable medical states no Raynauds disease

Exclusion criteria:

use other substance such as stimulants memantine allergy pregnancy

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients inter to our study based on simple accidently & respectively. Because of defined the number of patients of sample size in every group & they inter one by one ,before starting study, the order of 34 patients had set. For 17numbers drug & for other 17numbers placebo will give accidently. So before inter one person to study, intake of drug or placebo had set by predetermined list.

Blinding (investigator's opinion)

Single blinded

Blinding description

We accidently divide patients to 2 groups of control and intervention. The patients do not know about intake drug or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

darvaze ark. beheshti hospital

City

zanjan

Province

Zanjan

Postal code

4513615788

Approval date

2021-09-21, 1400/06/30

Ethics committee reference number

IR.ZUMS.REC.1400.264

Health conditions studied

1

Description of health condition studied

Effectiveness of memantine on OIH in opioid addict patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

severity of pain ranking by patients from 0 to 10

Timepoint

checking of patients one day before start memantine & at the end of second & forth week after treatment

Method of measurement

ranking by patients from 0 to 10

2

Description

time of stay patients hand in cold water

Timepoint

checking of patients one day before start memantine & at the end of second & forth week after treatment

Method of measurement

Cold pressor test time in seconds

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 18 to 60 years old opioid addict patients in Beheshti hospital with intake of enough analgesics from NSAIDS with maximum allowed dose, that have complaints of pain, & with OIH diagnose based on cold pressor test, divided 2 groups randomize & this group will receive memantine 10 MG daily.

Category

Treatment - Drugs

2

Description

Control group: Intervention group: 18 to 60 years old opioid addict patients in Beheshti hospital with intake of enough analgesics from NSAIDS with maximum allowed dose, that have complaints of pain & with OIH diagnose based on cold pressor test, divided 2 groups randomize & this group will receive placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti hospital

Full name of responsible person

Ahmad Zolghadriha

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Vice chancellor for research Zanjan University of Medical Sciences.Dr.Alireza Shoghli

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Ahmad Zolghadriha

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Nafise sadat Haji seyed taghia

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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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