Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of memantine utilization on pain tolerance time in methadone-maintained patients

Protocol summary

Study aim
Determining the average time of onset of cold pain and average duration of tolerating cold pain in patients Recipient of memantine and placebo before and five weeks after intervention and comparison of two means

Design
Randomised, placebo-control trial, phase 3 on 104 patients, with blinded patients, the examiner and analyser

Settings and conduct
Location of study: Shabnam methadone maintenance therapy clinic. A private clinic under the supervision of the Isfahan University of Medical Science. The patients, the examiner, and the analyzer are blinded. The non-dominant limb is immersed in water at a temperature of about one degree Celsius and the time of onset of pain and the time of maximum pain tolerance are recorded. Prolongation of time of onset of pain and prolongation of the duration of maximum pain tolerance are considered as indicators of "Raising the pain tolerance threshold".

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between eighteen and sixty-five years Physical health Confirmation of patient addiction according to DSM V criteria Patient consent to participate in the study Exclusion criteria: History of a psychiatric illness(Axis I or II). The patient has one of the major physical diseases, including Peripheral neuropathies; Raynaud's syndrome; Neuropathic pain. The patient's dissatisfaction with participation in the study or withdrawal The patient becomes addicted to another substance or drug; including Amphetamines; cannabis; alcohol; benzodiazepines. The patient regularly uses narcotic or non-narcotic analgesics for medical reasons.

Intervention groups
Intervention group: Receive 5 mg daily memantine tablets in the first week and then increased by 5 mg per week up to 20 mg or as the patient tolerates The control group: Receive a placebo pill with the same appearance as the drug

Main outcome variables
Pain onset threshold and maximum pain tolerance

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20090801002266N17**
Registration date: **2022-02-26, 1400/12/07**
Registration timing: **retrospective**

Last update: **2022-02-26, 1400/12/07**
Update count: **0**

Registration date
2022-02-26, 1400/12/07

Registrant information
Name
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Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-11-06, 1400/08/15
Expected recruitment end date
2021-12-06, 1400/09/15
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of memantine utilization on pain tolerance time in methadone- maintained patients

Public title
Memantine effect on pain tolerance time in MMTP patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Undertreatment in MMT program for at least 6 months
No methadone dose modification in recent 6 months
Exclusion criteria:
Any analgesic medication use Sedative drugs use Substance use disorder Any kind of psychiatric disorders Any kind of neuropathy, Raynaud’s disease

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
Each victim is assigned a number and based on a random number table, patients will be divided into two groups of placebo and medicine. The process is such that both consecutive eligible entrants are considered as a block. The random method is such that if the random number is 4-0, it is assigned to group A and if it is 5-9, it is assigned to group B and then decodes A and B based on the type of treatment (in which group each patient was). The medicine and placebo are poured into uniform envelopes and the patient number is written on each envelope and delivered to patients every week. Only the facilitator is aware of the table and which group the patient has entered, and the patient's test evaluator and examiner and the patient and the analyzer are blind.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are blinded for what group they are put in. The cold pressor test utilizer is blinded for the patient's group Analyzer will be blinded

Placebo
Used

Assignment
Parallel

Other design features
cold pressor test will be done in all patients before drug adminstration and after 5 weeks of drug or plasibo adminstration

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Science
Street address
Unit 3, Elahie apartment, No 2 Ave, No 9 street, Shahed Blvd, Sepahan Shahr, Isfahan
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Province
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Approval date
2021-07-03, 1400/04/12

Ethics committee reference number
IR.MUI.MED.REC.1400.261

Health conditions studied

1

Description of health condition studied
pain tolerance time

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Mean threshold of pain in cold pressor test

Timepoint
In the beginning of study and after 5 weeks of memantine or placebo

Method of measurement
Cold peressor test; stopwatch

2

Description
Mean duration of maximum pain tolerance in Cold pressor test

Timepoint
In the beginning of the study and after 5 weeks of memantine or placebo administration

Method of measurement
Cold professor test will be performed for patients and the time of onset of pain and maximum pain tolerance will be measured with a stopwatch

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: memantine tablet administration. Start with 5 mg per day in the first week and adding 5 mg per day every week until patient tolerates or maximum dose 20 mg per day for 5 weeks from beginning
Category
Treatment - Drugs

2

Description
Control group: placebo administration with a completely similar appearance to memantine tablets produced by the Faculty of Pharmacy of Isfahan University of Medical Sciences. One pill in the first week and then increase one daily pill weekly to a maximum of 4 pills a day or no patient tolerance for 5 weeks from beginning.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shabnam drug use treatment clinic
Full name of responsible person
Arman Otroshi
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Sponsors / Funding sources

1

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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Gholam Reza Kheirabadi
Position
Professor of Psychiatry
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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