Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jul 2026

Evaluation of the Effect of Donepezil on the Methadone Consumption in Methadone Maintenance

Protocol summary

Study aim
1- Comparison of methadone consumption in the intervention and control groups 2- Comparison of recurrence of opioid use in methadone patients in intervention and control groups 3- Comparison of severity of addiction in methadone patients in intervention group and control group 4- Comparison of desire for consumption in patients in methadone group in intervention and control groups 5- Comparison of the observed side effects of methadone in the intervention and control groups

Design
A randomized, triple-blind, placebo-controlled clinical trial

Settings and conduct
MMT clinics. Evaluation at 0,4,10 and 14 weeks with Addiction Severity Index (ASI), Donepedzil Complications, Craving Visual Analogue

Participants/Inclusion and exclusion criteria
Inclusion Criteria 1. Opioid use disorder according to diagnostic criteria with a specifier on DSM-5 agonist therapy 2. Age range from 18 to 55 years 3. Lack of Intellectual Disability Based on a Researcher's Interview as well as Minimum Fifth Level Education 4. Methadone at any dose (at least 20 mg) that has been stable for at least two months Exclusion Criteria 1. Severe sensitivity to Donepezil 2. Patients taking Antidepressants, Carbamazepine, Dexamethasone, phenobarbital, Phenytoin, Rifampin, Clonidine, Succinylcholine and Betanecol 3. History of Donepezil in the past three months 4- Heart disease based on history and history of hospitalization for cardiac causes 5.Pregnancy and lactation 6. Any major psychiatric disorder according to the researcher's interview except smoking 7.-Using any kind of psychotherapy

Intervention groups
Intervention group will receive 5 mg of Donepezil capsule from day 1 to 28th day of intervention and will receive 10 mg of Donepezil capsule from day 29 after evaluation of mentioned cases until completion of study.

Main outcome variables
Opioids Craving, Methadone intake

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191217045766N1**
Registration date: **2021-11-24, 1400/09/03**
Registration timing: **prospective**

Last update: **2021-11-24, 1400/09/03**
Update count: **0**

Registration date
2021-11-24, 1400/09/03

Registrant information

Name
Modabber Arasteh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 87 3328 8188

Email address
modabber.arasteh@muk.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-16, 1400/09/25

Expected recruitment end date
2022-01-21, 1400/11/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Donepezil on the Methadone Consumption in Methadone Maintenance

Public title

Evaluation of the Effect of Donepezil on the Methadone Consumption

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All opioid dependent patients on Methadone agonist therapy in the age range of 18 to 55 years At least fifth grade elementary education

Exclusion criteria:

Intellectual Disability Use if Anti Depressant, Carbamazepin, Dexamethasone, Phenobarbital, Phenytoin, Rifampin, Clonidine, Sox, Betanecol Use of Donepezil during 3 months ago CAD Pregnancy and Lactation major psychiatric disorder Use of Psychotherapy Sever sensitivity to Donepezil

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, physicians, and analysts are unaware of who is receiving what medication. Therefore, the study is performed in a triple blinded

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic commitment of Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences, Pasdaran Blv

City

Sanandaj

Province

Kurdistan

Postal code

6618634683

Approval date

2020-03-14, 1398/12/24

Ethics committee reference number

IR.MUK.REC.1398.307

Health conditions studied

1

Description of health condition studied

amount of Methadon use

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

amount of Methadon use

Timepoint

at the beginning of the study,weeks of 4, 10 and 14

Method of measurement

patients report

2

Description

craving for Methadon

Timepoint

at the beginning of the study,weeks of 4, 10 and 14

Method of measurement

HALIKAS Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Dopezil Sobhan Pharmaceutical Company Start with 5 mg oral tablets once a day for 4 weeks and then 10 mg tablets once a day until the end of week 14
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Qods hospital
Full name of responsible person
Razie Safari
Street address
Shohadaie Niruie Entezami Blv, Pasdaran Blv
City
Sanandaj
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6617713141
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+98 87 3366 0026
Email
raziesafari68@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kurdistan University of Medical sciences
Full name of responsible person
Afshin Maleki
Street address
Pasdaran Blv
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Sanandaj
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6618634683
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Email
info@muk.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kurdistan 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
Kurdistan University of Medical Sciences
Full name of responsible person
Modabber Arasteh
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Qods hospital., Shohadaie Niruie Entezani Blvd., Pasdaran Blvd
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Person responsible for scientific inquiries

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Position
Professor
Latest degree
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Email

arastehmd@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Modabber Arasteh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Qoda hospital., Shohadaie Niruie Entezami Bhvd., Pasdaran Blvd

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available