

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), Donepezil 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 Nirue Entezami Blv, Pasdaran Blv

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Sanandaj

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Kurdistan

Postal code

6617713141

Phone

+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

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6618634683

Phone

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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

Street address

Qods hospital., Shohadaie Nirue Entezani Blvd.,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

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Position

Professor

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Person responsible for updating data

Contact

Name of organization / entity

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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