Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effectiveness of Modafinil with placebo on sleep of patients diagnosed with methamphetamine dependency

Protocol summary

Study aim
the effect of Modafinil on sleep pattern in methamphetamine withdrawal

Design
the double-blinded randomized controlled study with control group, With parallel groups, sample size was 80 patients

Settings and conduct
study was done on patients were referred to psychiatry Hospital, Sari, Iran and treated with modafinil (200mg/day). Pittsburgh sleep quality index and Epworth sleepiness scale were used to assess sleep pattern in 1th and 56th day of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria were eighteen to sixty five years of age, recent methamphetamine dependency based ,continue to attend the study until the end, male gender. Exclusion criteria were abuse of different kinds of drugs along with methamphetamine simultaneously, The presence of a significant physical illness such as serious coronary, liver disease, uncontrolled diabetes, uncontrolled hypertension and increased liver enzymes more than three time normal before the entrance to the study,having suicidal thoughts or recent suicide attempt

Intervention groups
The intervention group received 200 mg of modafinil daily by the end of the week eight.The control group received 200 mg of placebo per day by the end of week eight. Psychiatric interview was conducted for all patients. Patients were not aware of the type of medicine (monafenil/placebo). This study was designed to evaluate the effect of modafinil on improving the sleep pattern of methamphetamine withdrawal or its possible complications.

Main outcome variables
methamphetamine withdrawal; recurrence; sleep pattern

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181218042036N1**
Registration date: **2019-03-16, 1397/12/25**
Registration timing: **retrospective**

Last update: **2019-03-16, 1397/12/25**
Update count: **0**
Registration date
2019-03-16, 1397/12/25

Registrant information
Name
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-09-06, 1397/06/15
Expected recruitment end date
2018-10-07, 1397/07/15
Actual recruitment start date
2018-09-06, 1397/06/15
Actual recruitment end date
2018-09-30, 1397/07/08
Trial completion date
2018-11-11, 1397/08/20

Scientific title

Comparison of the effectiveness of Modafinil with placebo on sleep of patients diagnosed with methamphetamine dependency

Public title
Modafinil effect on sleep of patient with methamphetamine dependency
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
eighteen to sixty five years of age recently methamphetamine dependency based on the diagnostic and statistical manual of mental disorders, 5th edition, text revision (DSM-5) and SCID criteria methamphetamine dependency based on the diagnostic and statistical manual of mental disorders, 5th edition, text revision (DSM-5) and SCID criteria The desire to attend this study Continuation of the study until the end
Exclusion criteria:
The presence of a significant physical illness such as serious coronary, liver disease, uncontrolled diabetes, uncontrolled hypertension and increased liver enzymes more than three time normal significant neurologic or psychiatric primary illness based on SCID by a psychiatrist, having suicidal thoughts and aggression
Age
From **18 years** old to **65 years** old
Gender
Male

Phase
4
Groups that have been masked

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

Sample size
Target sample size: **80**
Actual sample size reached: **77**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients have randomized in 20 blocks (4 patients per block) into intervention and control group using a random number table.
Blinding (investigator's opinion)
Double blinded
Blinding description
Randomization was performed by an independent person, who was not involved elsewhere in the trial. Participants did not know the type of medicine used (monafinil / placebo). Clinical care did not know the type of medicine used (monafinil / placebo).Investigator of the outcome did not know the type of medicine used (monafinil / placebo).The data analyst did not know the type of medicine used (monafinil / placebo).Concealment of allocation was performed using sequentially numbered, sealed, opaque and stapled envelopes. Separate people were responsible for generation of randomization codes, treatment allocation and interviewing. The patients, research investigators and interviewers were all blinded to the treatment allocation. Modafinil and placebo were completely identical in their size, color, shape, texture and odor.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciencesthe
Street address
Moalem Street
City
Sari
Province
Mazandaran
Postal code
4815838531
Approval date
2018-06-18, 1397/03/28
Ethics committee reference number
IR.MAZUMS.REC.1397.163

Health conditions studied

1

Description of health condition studied
sleep
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sleep pattern
Timepoint
in 1th and 56th day of the study
Method of measurement
Pittsburgh sleep quality index (PSQI) and Epworth sleepiness scale (ESS) were used to assess sleep pattern

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The participants started 100 mg of modafinil by a day. Psychiatric interview was done for all patients according to DSM-5 and SCID. Prescriptive modafinil used from Sobhan pharmaceutic company in Iran.
Category
Treatment - Drugs

2

Description
Control group: The participants started 100 mg of placebo by a day and after three days, they received 200 mg of placebo by a day until the end of week 8. Psychiatric interview was done for all patients according to DSM-5 and SCID. Prescriptive placebo used from Sobhan pharmaceutic company in Iran.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Zare Psychiatry Hospital, Sari, Iran
Full name of responsible person
Fatemeh Amini
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
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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
Sari 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
Mazandaran University of Medical Sciences
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fatemeh Amini
Position
Research Expert
Latest degree
Master
Other areas of specialty/work
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Other areas of specialty/work

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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

Dissatisfaction of the participants in the study

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

Yes - There is 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

Title and more details about the data/document

the clinical study report will be presented in a clear paper

When the data will become available and for how long

The documentation will be submitted within 6 months

To whom data/document is available

Due to informed consent and initial contract, participants didn't allow the public to access their questionnaires

Under which criteria data/document could be used

Due to informed consent and initial contract, participants didn't allow the public to access their questionnaires

From where data/document is obtainable

Due to informed consent and initial contract, participants didn't allow the public to access their questionnaires

What processes are involved for a request to access data/document

Due to informed consent and initial contract, participants didn't allow the public to access their questionnaires

Comments