Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of rTMS on amphetamine craving in patients with amphethamine dependency

Protocol summary

Study aim
Investigation of the effect of rTMS on Amphetamine craving in patients with amphethamine dependency

Design
Two arm parallel groups randomised trial with blinded postoperative care and outcome assessment The first group: rTMS on DLPFC with 10 Hz frequency for 20 minutes The second group: rTMS on orbitofrontal with 1 Hz frequency for 20 minutes Control group: Sham on DLPFC for 20 minutes

Settings and conduct
The study is a double blind clinical trial, and patients will be chosen from the clients of the addiction clinic of the Iranian Psychiatric Hospital . Based on the inclusion and exclusion criteria, the study process will be described for each person and if informed consent is given for participation, he / she will be entered into the study. He / She will be randomly assigned to 3 groups. Two active rtms and the sham group.

Participants/Inclusion and exclusion criteria
Patients who come to MMT center of Iran hospital, Exclusion criteria: Current psychosis, Other substance dependency except for nicotine and caffeine, Contraindication of rTMS Inclusion criteria: Being right handed, Having DSM-IV criteria of amphethamine dependency, At least two weeks of amphethamine withdrawal

Intervention groups
The first group: rTMS on DLPFC with 10 Hz frequency for 20 minutes The second group: rTMS on orbitofrontal with 1 Hz frequency for 20 minutes control group: Sham on DLPFC for 20 minutes

Main outcome variables
Craving Number of hospitalization in past 6 months

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180630040291N1**
Registration date: **2019-09-09, 1398/06/18**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-09, 1398/06/18**
Update count: **0**

Registration date
2019-09-09, 1398/06/18

Registrant information

Name
Atefeh Ghanbari Jolfaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6651 9519

Email address
Ghanbari.a@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01

Expected recruitment end date
2020-02-20, 1398/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of rTMS on amphetamine craving in patients with amphethamine dependency

Public title

The effect of rTMS on Amphetamine craving

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being right handed, Having DSM-IV criteria of amphethamine dependency, At least two weeks of amphethamine withdrawal; Having amphethamine craving

Exclusion criteria:

Current psychosis, Other substance dependency except for nicotine and caffeine, Contraindication of rTMS, Recent change of medication in past two weeks

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Restricted randomization based on random allocation rule

Blinding (investigator's opinion)

Double blinded

Blinding description

Using sham coil

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciencs

Street address

Hemmat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-01-15, 1396/10/25

Ethics committee reference number

IR.IUMS.REC 1396.31287

Health conditions studied

1

Description of health condition studied

Amphethamine craving

ICD-10 code

F19.1

ICD-10 code description

Other psychoactive substance abuse

Primary outcomes

1

Description

Amphetamine craving

Timepoint

Before rTMS and at least 1 week after the end of rTMS

Method of measurement

VAS Visual cue_indused craving assessment

Secondary outcomes

1

Description

Number of hospitalizations

Timepoint

Six months after rTMS

Method of measurement

Counting

Intervention groups

1

Description

Intervention group: The patients will be selected among clients referring to the addiction clinic (MMT) of Tehran Psychiatric Hospital and Tehran Behavioral Sciences Institute, and Iran's Psychiatric Center using convenient sampling method. The research inclusion criteria included 1- People aged 18 to 60 years who have the amphetamines dependence criteria based on DSM-V before the treatment and have undergone treatment and have not used amphetamine at least for 2 weeks 2- The patient report the methamphetamine craving. Exclusion criteria included: Current psychosis, Other substance dependency except for nicotine and caffeine, Contraindication of rTMS, Recent change of medication in past two weeks

Category

Treatment - Devices

2

Description

Intervention group: The patients will be selected among clients referring to the addiction clinic (MMT) of Tehran Psychiatric Hospital and Tehran Behavioral Sciences Institute, and Iran's Psychiatric Center using convenient sampling method. The research inclusion criteria included 1- People aged 18 to 60 years who have the amphetamines dependence criteria based on DSM-V before the treatment and have undergone treatment and have not used amphetamine at least for 2 weeks 2- The patient report the methamphetamine craving.Exclusion criteria included: Current psychosis, Other substance dependency except for nicotine and caffeine, Contraindication of rTMS, Recent change of medication in past two weeks

Category

Treatment - Devices

3

Description

Control group: The patients will be selected among clients referring to the addiction clinic (MMT) of Tehran Psychiatric Hospital and Tehran Behavioral Sciences Institute, and Iran's Psychiatric Center using convenient sampling method. The research inclusion criteria included 1- People aged 18 to 60 years who have the amphetamines dependence criteria based on DSM-V before the treatment and have undergone treatment and have not used amphetamine at least for 2 weeks 2- The patient report the methamphetamine craving. Exclusion criteria included: Current psychosis, Other substance dependency except for nicotine and caffeine, Contraindication of rTMS, Recent change of medication in past two weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Iran Psychiatric Hospital
Full name of responsible person
Atefeh Ghanbari
Street address
Old road of Karaj
City
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1398913151
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Atefeh Ghanbari Jolfaei
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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

Iran 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
Iran University of Medical Sciences
Full name of responsible person
Atefeh Ghanbari Jolfaei
Position
Associate professor of psychiatry
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Original article
When the data will become available and for how long
At the end of the project
To whom data/document is available
The readers of the journal in which the article will be accepted
Under which criteria data/document could be used
Guideline of the journal
From where data/document is obtainable
It is not determined yet
What processes are involved for a request to access data/document
Guideline of the journal
Comments