Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Comparative Study on the Effectiveness of Adding Valproate and Placebo on Reduction of the Craving in Methamphetamine-Dependent Patients during Treatment with Matrix Program

Protocol summary

Summary

The aim of this study was to investigate the efficacy of adding Valproate or placebo in reducing the usage tendency in methamphetamine-depended patients during treatment with Matrix program. Inclusion criteria include men and women age 18–40 years old who were diagnosed with methamphetamine dependency according to DSM-IV criteria and exclusion criteria include a current neurological or axis I psychiatric disorders not due to substance abuse that would impair ability to participate safely in the study and subjects who met DSM-IV criteria for opiates dependence. The 40 subjects were selected from patients who referred to Addiction Treatment Center of Isfahan Noor hospital to attend meetings of matrix program during 2012 to 2013. After screening the subjects were participated in matrix program and randomly were divided into two groups of Valproat and placebo. A 4-months program of intervention was arranged for each group and they were visited by a psychiatrist every two weeks. Valproate was started with the dose of 250 mg and within 10 days it increased to the dose of 1000 mg, and this amount continued for 4 months. The craving was assessed by Cocaine Craving Questionnaire-Brief (CCQ-Brief) at screening and every 2 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406027841N7**
Registration date: **2014-06-06, 1393/03/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-06-06, 1393/03/16

Registrant information

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, Behavioral Sciences Research Center

Expected recruitment start date

2012-12-01, 1391/09/11

Expected recruitment end date

2013-09-30, 1392/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study on the Effectiveness of Adding Valproate and Placebo on Reduction of the Craving in Methamphetamine-Dependent Patients during Treatment with Matrix Program

Public title

Comparing of Valproate with Placebo in Reducing

Methamphetamine Craving

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: men and women age 18–40 years old; diagnosed with methamphetamin dependency according to DSM-IV criteria; informed acceptance to comply with study procedures. Exclusion criteria: sever medical illness that would impair the ability to participate safely in the study; a current neurological or axis I psychiatric disorders not due to substance abuse (e.g., schizophrenia, dementia) that would impair ability to participate safely in the study; current pregnancy or nursing in women; current serious suicidal intention or plan; more than 3 times elevation of AST and ALT at screening; subjects who met DSM-IV criteria for opiates dependence.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezar jerib Street

City

Isfahan

Postal code

Approval date

2012-11-05, 1391/08/15

Ethics committee reference number

7/3357/د

Health conditions studied

1

Description of health condition studied

Methamphetamine Dependency

ICD-10 code

F15.2

ICD-10 code description

Mental and behavioural disorders due to use of other stimulants, including caffeine.Dependence syndrome

Primary outcomes

1

Description

Methamphetamine Craving

Timepoint

At screening and every 2 weeks up to 4 months

Method of measurement

Cocaine Craving Questionnaire-Brief (CCQ-Brief)

Secondary outcomes

1

Description

Drowsiness

Timepoint

At screening and every 2 weeks up to 4 months

Method of measurement

History and Physical examination

2

Description

Dyspepsia

Timepoint

At screening and every 2 weeks up to 4 months

Method of measurement

History and Physical examination

3

Description

Weight gain

Timepoint

At screening and every 2 weeks up to 4 months

Method of measurement

History and Physical examination

4

Description

Tremor

Timepoint

At screening and every 2 weeks up to 4 months

Method of measurement

History and Physical examination

Intervention groups

1

Description
Intervention group: valproate tabs was started with the dose of 250 mg and within 10 days it increased to the dose of 1000 mg and this amount continued for 4 months.
Category
Treatment - Drugs

2

Description
Control group: A placebo with similar medicinal form to Valproat started and continued for 4 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatric Drug Treatment Center, Emergency and Clinic of Noor Hospital
Full name of responsible person
Masood Ghavami
Street address
Ostandari street, Noor Hospital
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences, Behavioral Sciences Research Center
Full name of responsible person
Dr Abas Atari
Street address
Ostandari Street, Noor Hospital
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences, Behavioral Sciences Research Center
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty