

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of efficacy of Riluzole compared with placebo in the treatment of Methamphetamine dependence: A randomized, double-blind, placebo-controlled trial

Protocol summary

Summary

Summary With the goal of evaluation of the effect of Riluzole in the treatment of methamphetamine dependency, 40 patients are investigated in the present study. All patients only have Methamphetamine consumption in their recent addiction history. 20 patients are treated with placebo and non-medication (psychological) interventions and the other 20 individuals, in addition to non-medication (psychological) interventions, consume Riluzole. The duration of therapy is 3 months and the dosage of Riluzole is twice per day. In both groups, in spite of drug intervention and visit by physicians, patients refer to the center twice a week and take part in personal behavioral psychocognitive meetings with the modified matrix method. Matrix therapy is a non-medication (psychological) therapy method that based on the planned sessions issues like individual psychotherapy and family counseling is covered. In this study, patients take part in matrix meetings twice a week. The study is a clinical trial and a human sampling method that will be conducted at university addiction's therapy center in the city of Yazd. In this study, patients with methamphetamine dependency will be randomly divided in two groups of oral Riluzole or placebo according to diagnostic DSM-IV-TR criteria. This is a double blind study in which except information committee personnel (analysts) all other groups including patients, therapists, and also researchers do not know anything about the quality of patients' layout in different groups. Consequences are based on adherence to therapeutic regimen including: Percentage of physician visit and counseling that patient participate to all planned sessions, ratio of negative urinary sample results for Methamphetamine, Morphine, Cannabis and benzodiazepines that take place twice a week, addiction severity measured by addiction severity index (ASI), level of Methamphetamine withdrawal, and

depression measured by Hamilton depression 17-items questionnaire (Hamilton Depression rating Scale). Inclusion criteria: Dependence to Methamphetamine according to DSM-IV criteria, consent and commitment for treatment cooperation, age above 18 and under 65. Exclusion criteria: Past history of sensitivity to Riluzole , past history of structural or functional liver disease or abnormal liver function tests (Ast, Alt) , 5-fold increase in liver enzymes test (Ast,Alt) or jaundice. Inclusion and exclusion criteria are evaluated based on the following methods: 1. Examination by the physician of the center. 2. Interview by the clinical psychiatrist of the center. 3. Performing required clinical laboratory tests and electrocardiography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012826168N1**

Registration date: **2016-05-01, 1395/02/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-01, 1395/02/12

Registrant information

Name

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Name of organization / entity

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Email address mh-farahzadi@razi.tums.ac.ir	Randomization description Blinding (investigator's opinion) Double blinded
Recruitment status Recruitment complete	Blinding description Placebo Used
Funding source Tehran university of medical Science	Assignment Parallel
Expected recruitment start date 2016-02-20, 1394/12/01	Other design features
Expected recruitment end date 2016-09-22, 1395/07/01	Secondary Ids empty
Actual recruitment start date empty	Ethics committees
Actual recruitment end date empty	1
Trial completion date empty	Ethics committee
Scientific title Evaluation of efficacy of Riluzole compared with placebo in the treatment of Methamphetamine dependence: A randomized, double-blind, placebo-controlled trial	Name of ethics committee Tehran University of Medical Sciences
Public title Evaluation of efficacy of Riluzole in the treatment of Methamphetamine	Street address Tehran University of Medical Sciences; Tehran; Iran
Purpose Treatment	City Tehran
Inclusion/Exclusion criteria Inclusion criteria: Dependence to Methamphetamine according to DSM-IV criteria, consent and commitment for treatment cooperation, age above 18 and under 65. Exclusion criteria: Past history of sensitivity to Riluzole: past history of structural or functional liver disease or abnormal liver function tests (Ast, Alt). 5fold increase in liver enzymes test (Ast,Alt) or jaundice; abnormal renal function tests at the beginning of the study; interstitial lung disease or hypersensitive pneumonitis; neutropenia; pregnancy or lactation; developing psychiatric disorders or previous neurologic disorders like psychosis; bipolar disorders; major depression, tic disorders; Tourette's syndrome or any psychiatric disorders that need medical therapy or makes dependency to addiction therapy complicated; developing significant clinical cardiovascular disorders; physical exam or electrocardiography; family history of disability or premature cardiovascular mortality in first degree relatives; past history of severe untreated physical disabilities; abnormal vital signs.	Postal code 1417575694
Age From 18 years old to 65 years old	Approval date 2016-01-10, 1394/10/20
Gender Both	Ethics committee reference number IR.Tums.REC.1394.94-2-87-28567-181124
Phase N/A	Health conditions studied
Groups that have been masked No information	1
Sample size Target sample size: 40	Description of health condition studied Psychoactive substance use
Randomization (investigator's opinion) Randomized	ICD-10 code F10, F11,
	ICD-10 code description Mental and behavioural disorders due to psychoactive substance use
	Primary outcomes
	1
	Description Adherence to treatment
	Timepoint Once a week
	Method of measurement Refer the patient to receive the drug(questionnaire)
	2
	Description The proportion of negative urine test results
	Timepoint Once a week
	Method of measurement

urine test

3

Description

Depression

Timepoint

Beginning and end of treatment

Method of measurement

Hamilton Depression Rating Scale

4

Description

Craving for methamphetamine

Timepoint

Monthly

Method of measurement

questionnaire

5

Description

Addiction Severity

Timepoint

Monthly

Method of measurement

ASI: Addiction Severity Index

6

Description

Methamphetamine dependence

Timepoint

Monthly

Method of measurement

ASI: Addiction Severity Index Questionnaire

Secondary outcomes

1

Description

Clinical examination of the pulse, and blood pressure

Timepoint

On admission and then weekly

Method of measurement

Clinical examination

2

Description

Riluzole side effects

Timepoint

Weekly

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: 20 patients are treated with Riluzole.

The duration of therapy is 3 months and the dosage of Riluzole is twice per day.

Category

Treatment - Drugs

2

Description

Control group: 20 patients are treated with placebo. The duration of therapy is 3 months and the dosage of placebo is twice per day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iman Addiction Treatment Center

Full name of responsible person

Mohammadhadi Farahzadi

Street address

Addiction Treatment Center; Edalat Square;
Azadshahr; Yazd; Iran

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of
Medical Sciences

Full name of responsible person

Shahin Akhondzadeh

Street address

Tehran University of Medical Sciences; Tehran; Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical
Sciences

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

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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