Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Investigating the effect of nano curcumin supplementation on drug craving, psychotic symptoms and serum levels A2A, TLR4 receptors and TNF-alpha, IL-6 factors in psychotic methamphetamine consuming patients.

Protocol summary

Study aim
Determination of the effectiveness of nano curcumin supplement on drug craving, psychotic symptoms and serum levels of pro-inflammatory factors and A2A, TLR4 receptors in psychotic methamphetamine consuming patients

Design
This clinical trial has a control group in a double-blind, randomized phase 3 method on 50 psychotic methamphetamine patients in two groups, where randomization is done by block method.

Settings and conduct
A study with the design of a controlled clinical trial - double-blind placebo treatment on 50 psychotic methamphetamine consuming patients referred to Kashan Psychiatric Hospital who were admitted and then randomly divided into two groups. Researchers and participants are unaware of the drug and placebo groups. Nanocurcumin capsule drug or placebo with identification code A or B is prescribed for 4 weeks. Blood samples will be taken at the beginning of the study and 4 weeks after the intervention of the patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: completion of the consent form; having symptoms of methamphetamine psychosis with the diagnosis of the senior research psychiatrist for hospitalization; Having a craving score between 10 and 70 based on a momentary measurement questionnaire to enter the intervention. Exclusion criteria: unwillingness to cooperate in any stage of project implementation; People who are allergic to drugs during the study; any past or present psychotic disorder; pregnant women.

Intervention groups
Study patients are randomly divided to receive nanocurcumin supplement 40 mg twice a day (N=25) or placebo (N=25) orally for a period of 4 weeks.

Main outcome variables
Craving score and recovery of psychotic symptoms of patients; Inflammatory factor TNF alpha; inflammatory factor IL-6; Determination of serum A2A and TLR4 receptors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240208060938N1**
Registration date: **2024-02-28, 1402/12/09**
Registration timing: **prospective**

Last update: **2024-02-28, 1402/12/09**
Update count: **0**

Registration date
2024-02-28, 1402/12/09

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2024-04-03, 1403/01/15

Expected recruitment end date

2024-07-05, 1403/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of nano curcumin supplementation on drug craving, psychotic symptoms and serum levels A2A, TLR4 receptors and TNF-alpha, IL-6 factors in psychotic methamphetamine consuming patients.

Public title

Investigating the effect of nanocurcumin in psychotic methamphetamine users

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Being at least 18 years old based on symptoms of methamphetamine psychosis to be admitted to the psychiatric ward. Use of methamphetamine more than two days a week for more than 1 year, as dependent on methamphetamine. Diagnosis of chronic methamphetamine use disorder based on the diagnostic criteria of the Diagnostic and Statistical Manual of Mental Disorders, fifth edition Based on the diagnosis of the senior research psychiatrist, having the symptoms of methamphetamine psychosis to be admitted to the psychiatric ward, one of the criteria of which is the positive and negative syndrome (PANSS), which was initially created for use in patients with schizophrenia, is one of the most reliable tools to assess the existence and the severity of psychotic symptoms. Having a minimum score of 10 and a maximum score of 70 for drug craving based on the questionnaire measuring the momentary drug craving (DDQ) to enter the intervention. People should not have a history of drug use (opium, opium juice, heroin, crack, and hashish). Completing the consent form.

Exclusion criteria:

Unwillingness to cooperate at any stage of project implementation. Be dependent on drugs other than methamphetamine. People who are allergic to study and report side effects caused by taking medicine while studying. Taking curcumin and antioxidant and anti-inflammatory supplements in the last 3 months. The urine test for morphine, hashish and other drugs except methamphetamine will be checked three times for each person during the study, and if the test is positive, the patient will be excluded from the study. Pregnant women. Any past or current psychotic disorder, including manic episodes, schizophrenia, and schizoaffective disorder.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, the table of random numbers and block randomization method are used. In this method, 50 eligible patients are randomly divided into 25 blocks including 2 patients. Then, each of the 2 patients in the herbal drug block receives nano curcumin or placebo, so that 25 patients are assigned to each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The packaging of nano curcumin herbal medicine and placebo is prepared with a label with code B or A. Other specifications on the labels are the same. Researchers, doctors, nurses, patients, those responsible for data collection and those who evaluate the outcome are unaware of the drug and placebo groups. Only the expert responsible for packaging the capsules knows the contents of the packages or the code A or B. Patients are aware that they are either in the herbal medicine group or in the placebo group, but they do not know the type of group they are in.

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

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Approval date

2024-01-28, 1402/11/08

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1402.258

Health conditions studied

1

Description of health condition studied

Psychotic methamphetamine users

ICD-10 code

F10-F19

ICD-10 code description

اختلالات روانی و رفتاری ناشی از مصرف مواد روانگردان

Primary outcomes

1

Description

Methamphetamine dependence and craving score

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study, 4 weeks after taking nanocurcumin and one month later without drug intervention.

Method of measurement

Craving score is used to measure craving through visual analog scales (VAS).

Secondary outcomes

1

Description

Serum TNF alpha inflammatory factor

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study after 4 weeks of drug intervention

Method of measurement

To measure serum TNF alpha from the patient's blood serum sample using an ELISA device (immunoassay method) and it is expressed in nanograms per milliliter.

2

Description

Serum IL-6 inflammatory factor

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study after 4 weeks of drug intervention

Method of measurement

To measure serum interleukin 6 from a patient's blood serum sample using an ELISA device (immunoassay method) and it is expressed in nanograms per milliliter.

3

Description

Adenosine A2A receptor (A2A) serum

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study after 4 weeks of drug intervention

Method of measurement

To measure the serum A2A receptor from the patient's blood serum sample using an ELISA device (immunoassay method) and it is expressed in nanograms per milliliter.

4

Description

Toll-like receptor (TLR4) serum

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study after 4 weeks of drug intervention

Method of measurement

To measure the TLR4 serum receptor from the patient's blood serum sample using an ELISA device (immunoassay method) and it is expressed in nanograms per milliliter.

Intervention groups

1

Description

Intervention group:In addition to the standard mood stabilizing and antipsychotic drugs, the patients of this group receive two 40 mg nanomicelle curcumin capsules made by Oxirnano Sina twice a day for 4 weeks as a supplement during hospitalization.

Category

Treatment - Drugs

2

Description

Control group: Patients of this group, in addition to mood stabilizers and antipsychotic drugs, two 40 mg capsules of placebo (containing cellulose) with curcumin characteristics in terms of color, shape and other characteristics manufactured by Oxyrnano Sina company twice a day for 4 weeks of intervention. They receive it as a supplement during hospitalization.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Karganjad Hospital, Kashan University of Medical Sciences

Full name of responsible person

Mojtaba Mahdavi

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1

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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
Kashan 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available