Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Study of Hypiran (Hypericum Perforatum) effect on oxidative stress and neurotrophic factors in Methamphetamine associated psychosis patients

Protocol summary

Summary

The main aim of the study is to evaluate oxidative stress and neurotrophic factors after intervention in methamphetamine associated psychosis (MAP) patients who receive Hypiran in addition to the anti psychotic medications. This study is a double blind clinical trial in two groups of patients with MAP and obtaining informed consent of patients before subjecting them to any intervention. Inclusion criteria are current methamphetamine users who have been hospitalized. Exclusion criteria comprise previous history of bipolar disorder, mania symptoms in the current context based on clinical examination, and liver and kidney diseases. Before the intervention, the patients will be investigated for liver and kidney function tests such as AST, ALT, ALP, and urea and creatinine .Eligible patients in the study are randomly placed in control and case groups. The sample size is 20 people in each group. Then the blood sample will be collected from the two groups of the patients when they are admitted to the hospital and after withdrawal of methamphetamine. After blood drowns from the patients, the intervention will be done. The case group will received 60 drops of Hypiran in three dose and the control patients will get placebo in the same dose with Hypiran. After two weeks, the blood samples will be obtained from case and control groups. Finally, after one month of intervention the blood samples will be collected again from the two groups to evaluate oxidative stress and trophic factors.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082129447N1**
Registration date: **2016-10-31, 1395/08/10**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2016-10-31, 1395/08/10

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Study of Hypiran (Hypericum Perforatum) effect on oxidative stress and neurotrophic factors in Methamphetamine associated psychosis patients

Public title

The Study of Hypiran effect on Methamphetamine

associated psychosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the patients who are current methamphetamine users have been admitted to the hospital; age between 18 and 70 years old; they have met the criteria for methamphetamine induced psychotic disorder according to DSM-5. Exclusion criteria: having a diagnosis of bipolar I and II disorder; substance induced mood disorder (with manic symptoms); liver and kidney diseases.

Age

From **18 years** old to **70 years** old

Gender

Male

Phase

4

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

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Postal code

Approval date

2016-10-09, 1395/07/18

Ethics committee reference number

IR.IUMS.REC.1395.27866

Health conditions studied

1

Description of health condition studied

Methamphetamine associated psychosis

ICD-10 code

F16

ICD-10 code description

Mental and behavioural disorders due to use of hallucinogens

Primary outcomes

1

Description

Glutathione Peroxidase

Timepoint

before intervention, 14 and 28 days after intervention

Method of measurement

colorimetry

2

Description

Glutathione Reductase

Timepoint

before intervention, 14 and 28 days after intervention

Method of measurement

colorimetry

3

Description

Total Antioxidant Capacity

Timepoint

before intervention, 14 and 28 days after intervention

Method of measurement

colorimetry

4

Description

Nitric Oxide

Timepoint

before intervention, 14 and 28 days after intervention

Method of measurement

Elisa

5

Description

Malondialdehyde

Timepoint

before intervention, 14 and 28 days after intervention

Method of measurement

Elisa

6

Description

selenoprotein1

Timepoint

before intervention, 14 and 28 days after intervention

Method of measurement

Elisa

7

Description
Methamphetamine
Timepoint
14 after intervention
Method of measurement
HPLC

Secondary outcomes

1

Description
BDNF
Timepoint
before intervetion and 28 days after intervention
Method of measurement
ELISA

2

Description
VEGF
Timepoint
before intervetion and 28 days after intervention
Method of measurement
ELISA

3

Description
DTNBP1
Timepoint
before intervetion and 28 days after intervention
Method of measurement
ELISA

4

Description
IL-6
Timepoint
before intervetion and 28 days after intervention
Method of measurement
ELISA

Intervention groups

1

Description
Hypiran medication will be prescribed in the intervention group. The dosage of hypiran use is 60 drops three times a day for one month. (60 drops of hypiran has 0.3 mg of the active ingredient called Hypericin).
Category
Treatment - Drugs

2

Description
Placebo will be prescribed in the control group. The dosage of placebo use is 60 drops three times a day for one month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran psychiatric Hospital
Full name of responsible person
Dr. Mehrdad Eftekhar, Dr. Seyed vahid Shariat
Street address
District 21, Azadegan Freeway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Javad Mousavi
Street address
Hemmat Highway
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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
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