Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Haloperidol and Opium Tincture in the control of clinical signs associated with methamphetamine

Protocol summary

Summary

In this experimental study 70 methamphetamine-dependent patients admitted to addiction clinics or psychiatric clinics in the city was selected after completing an informed consent to participate in the study by the patient or guardian him, Randomized to two groups: standard treatment (Haloperidol) and intervention (Opium Tincture) are divided. Inclusion criteria: Methamphetamine dependence (More than 10 times the regular use of methamphetamine or 10 days); Positive Methamphetamine urine test; Age 18-65; Note dependency to other opioid and opium; Exclusion criteria: Other addictive drugs or alcohol or drug use during the study period; Non-compliance with medication orders during the study; There are other mental disorders that require treatment or the risk of suicide; Significant diseases of the Thyroid, Kidney, Liver, Gastrointestinal or Cardiovascular; History of diabetes or Heart attack; In the first and last study completed questionnaires contained demographic information, past history, physical exam and psychological exam. This information contain weight, Appetite, sleep, daily activity, psychotic reaction, anxiety and craving. The paitents deveised two groups (standard treatment and intervention). Standard group give Haloperidol 1mg during 1week, than 1mg/bid during 3 week .Intervention group give Opium tincture 14cc/day during 2week, than is low 1cc every 4 days. All data comparing the efficacy of two drugs became two groups will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080223470N1**
Registration date: **2015-09-11, 1394/06/20**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2015-09-11, 1394/06/20

Registrant information

Name
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Name of organization / entity
Arak University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-02-09, 1394/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Haloperidol and Opium Tincture in the control of clinical signs associated with methamphetamine

Public title

The effects of Opium Tincture in the control of clinical signs associated with methamphetamine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Dependence on methamphetamine (more than 10 times the regular use of methamphetamine or 10 days); Urine tests positive for methamphetamine; Age 18-65 years; Independence and no use of drugs or other addictive drugs at the time of presentation; Complete the consent form; To track patient; Exclusion criteria: Unwillingness person to continue treatment; Patient self-medication or participate in another study; Other addictive drugs or alcohol or drug use during the study period; Non-compliance with medication orders during the study; Coming out of treatment (imprisonment, death, ...); Any behavior that resulted in dismissal laws rehab clinic patient; There are other mental disorders that require treatment or the risk of suicide; Significant diseases of the Thyroid, Kidney, Liver, Gastrointestinal or Cardiovascular; History of diabetes or Heart attack, Seizures, Glaucoma, Tick, Tardive dyskinesia; Female without adequate contraception pregnancy or lactation; Tincture of opium abusers; A history of allergy to Haloperidol; Simultaneous treatment with antipsychotics or mood stabilizers or CYP 2D6 inhibitors Contains: Amiodarone, Bupropion, Celecoxib, Cimetidine, Chlorpromazine, Clomipramine, Fluoxetine, Haloperidol, Methadone, Moclobemide, Paroxetine, Quinidine, Ritonavir, Sertraline, Terbinafine and Thioridazine; So dangerous side effects of medications or the patient is intolerable.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Sardasht Site

City

Arak

Postal code

Approval date

2014-10-20, 1393/07/28

Ethics committee reference number

93-169-12

Health conditions studied

1

Description of health condition studied

Methamphetamin dependency

ICD-10 code

T43.6

ICD-10 code description

Psychostimulants with abuse potential

Primary outcomes

1

Description

Sleep condition improve

Timepoint

Befor and during and after invetervention

Method of measurement

Beck questionnaire

2

Description

Psychotic reaction

Timepoint

Befor and during and after invetervention

Method of measurement

Beck questionnaire and Psychological exam

3

Description

Craving

Timepoint

Befor and during and after invetervention

Method of measurement

Psychological exam

Secondary outcomes

empty

Intervention groups

1

Description

Standard group give Haloperidol 1mg during 1week, than 1mg/bid during 3 week.

Category
Treatment - Drugs

2

Description
Intervention group give Opium tincture 14cc/day during 2week, than is low 1cc every 4 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Public Free Clinic addiction
Full name of responsible person
Dr.Mohammad jamalian
Street address
Jahantash alley, Shariati st,
City
Arak

2

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Dr. mohammad fazli
Street address
Valiasr Square
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, University of Medical Sciences
Full name of responsible person
Mehdi shafiee
Street address
Arak University of Medical Sciences
City
Arak
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, 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

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. mohammad fazli
Position
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Other areas of specialty/work
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Assistant Professor
Other areas of specialty/work
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Web page address

Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Dr.mohammad fazli
Position

Medical student

Other areas of specialty/work

Street address

City

Arak

Postal code

Phone

00

Fax

Email

Web page address

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