

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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 patients devised 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

Mohammad Fazli

Name of organization / entity

Arak University of Medical Sciences

Country

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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

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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