

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effectiveness of opium tincture and methadone syrup for management of acute opium withdrawal.

Protocol summary

Summary

With respect to the issue that all published articles about the comparison of opium tincture and methadone syrup are open labeled, we decide to compare the effects of opium tincture and methadone syrup for management of acute opium withdrawal symptoms in a randomized double blind clinical trial. Seventy four opium dependent females or males with the age range of 18 to 60 years old will be included if they have no history of serious medical or psychiatric disorders. Patients will be randomly allocated to methadone syrup or opium tincture and received methadone (15, 30 and 45 mg) or opium Tincture (45, 90 and 135 mg) according to the severity of dependence based on Addiction Severity Index. Methadone (15, 30 and 45 mg) or Opium Tincture (45, 90 and 135 mg) will be administered for the patients, respectively. Both drugs will be continued with fix dose for 5 days and then be tapered 20% per day. At the end of tenth day both drugs will be discontinued. Appearance and odor of both drugs will be equalized by pharmaceutical industry experts. Patients and rater are blind to the drugs. Severity of withdrawal symptoms will be assessed daily by Objective Opioid Withdrawal Scale (OOWS). Adverse effects will be assessed by direct question and observation. Data will be analyzed by SPSS software. Comparison will be done by T-test and Chi-square. Major analysis of questionnaire's scores will be done by Repeated Measures Analysis of variance.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122511885N1**

Registration date: **2013-07-01, 1392/04/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-07-01, 1392/04/10

Registrant information

Name

Samaneh Farnia

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 11 3328 5659

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sfarnia@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2012-11-08, 1391/08/18

Expected recruitment end date

2013-03-08, 1391/12/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of opium tincture and methadone syrup for management of acute opium withdrawal.

Public title

Opium tincture and methadone syrup effectiveness for management of opium withdrawal

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Meeting the DSM-IV-TR criteria for opium dependence; first time detoxification; age range 18- 60 years . Exclusion criteria: Physical illnesses that needed methadone consumption; using other substances (other opioids, cannabinoids, alcohol, benzodiazepines and etc); major psychiatric disorders such as bipolar mood disorder, major depression, severe anxiety disorders and psychotic disorders; major physical diseases such as hepatitis, tuberculosis, AIDS and etc; pregnancy; lactation.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The block randomization method is used . Since the taste ,appearance and odor of both drugs is equalized patients and rater are blind to them.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Moallem Square

City

Sari

Postal code

4817844718

Approval date

2012-11-07, 1391/08/17

Ethics committee reference number

91-121

Health conditions studied

1

Description of health condition studied

opium Withdrawal

ICD-10 code

F11.3

ICD-10 code description

Mental and behavioural disorders due to psychoactive substance use; withdrawal state

Primary outcomes

1

Description

opium withdrawal sign & symptom

Timepoint

Daily (Within 10 days of drug administration)

Method of measurement

Objective Opioid Withdrawal Scale (OOWS)

Secondary outcomes

1

Description

Side effects of drugs

Timepoint

Daily (Within 10 days of drug administration)

Method of measurement

Questionnaire

Intervention groups

1

Description

In methadone group, regarding to a severity of dependence)Based on Addiction Severity Index(mild, moderate, severe, methadone syrup (Made by Exir Company) 15, 30 and 45 mg may be administered, respectively. Drug was continued in two divided doses for 5 days with a constant dose and then tapered 20% per day. At the end of Tenth Day drug was discontinued.

Category

Treatment - Drugs

2

Description

In Tincture of Opium group, regarding to a severity of dependence)Based on Addiction Severity Index(mild, moderate, severe, Tincture of Opium (Made by Daroupakhsh Company) 45, 90 and 135 mg may be administered, respectively. Drug was continued in two divided doses for 5 days with a constant dose and then tapered 20% per day. At the end of Tenth Day drug was discontinued.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

addiction clinic of Zare hospital

Full name of responsible person

Dr. Mehran Zarghami

Street address

Zare Hospital, Neka Road

City

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Other areas of specialty/work

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati MD

Street address

Mazandaran University of Medical Sciences, Moallem Square

City

Sari

Grant name

10506

Grant code / Reference number

10506

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

Yes

Title of funding source

Vice chancellor for research, Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Samaneh Farnia MD

Position

Psychiatrist/Assistant professor

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Mehran Zarghami

Position

Professor

Other areas of specialty/work

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Web page address

www.mazums.ac.ir

Person responsible for updating data

Contact

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