Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Name of organization / entity
Mazandaran University of Medical Sciences
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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
Sari

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
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Full name of responsible person
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+98 15 1328 5109
Email
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mehran.zarghami@gmail.com
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