

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of Opium Tincture (OT) and Methadone for Maintenance Treatment of Opioid Dependence: A Randomized Double-blind Controlled Clinical Trial

Protocol summary

Summary

In this randomized double-blind randomized controlled clinical trial, opioid-dependent patients seeking maintenance treatment will be screened. Our aim is to compare the efficacy and safety of opium tincture (OT) with methadone syrup for maintenance treatment. Inclusion Criteria: Opioid dependence as confirmed by DSM V diagnostic criteria Willingness and ability to adhere to study protocol and follow-up schedule as determined through the pre-randomization period Provide written informed consent. Females of childbearing capacity must agree to use an acceptable method of birth control approved by the study investigator throughout the study. Exclusion Criteria: Active participant in another treatment program for opioid dependence within 14 days before inclusion in the study Severe hepatic impairment (decompensated liver disease Hypersensitivity to methadone syrup or other ingredients in the formulation Pregnancy Severe chronic respiratory disease Head injury and raised intracranial pressure Biliary tract disease Monoamine oxidase inhibitors use within 14 days of the study Then, 240 eligible participants will be randomly allocated to either opium (intervention) or methadone (active comparator) group. Both groups will be followed for 12 weeks and will receive routine psychosocial interventions. Each participant will attend a total of 31 visits and the primary outcome will be retention in treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506261556N78**

Registration date: **2015-07-26, 1394/05/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-07-26, 1394/05/04

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

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Recruitment status

Recruitment complete

Funding source

Number 206, 1st floor, Administrative Bldg., Tehran University of Medical Sciences, Keshavarz Boulevard, Tehran, Iran

Expected recruitment start date

2015-09-01, 1394/06/10

Expected recruitment end date

2017-09-01, 1396/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Opium Tincture (OT) and Methadone for Maintenance Treatment of Opioid Dependence: A Randomized Double-blind Controlled Clinical Trial

Public title
Opium trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Opioid dependence as confirmed by DSM V diagnostic criteria; Willingness and ability to adhere to study protocol and follow-up schedule as determined through the pre-randomization period; Provide written informed consent; Females of childbearing capacity must agree to use an acceptable method of birth control approved by the study investigator throughout the study. Exclusion criteria: Active participant in another treatment program for opioid dependence within 14 days before inclusion in the study; Severe hepatic impairment (decompensated liver disease): a contraindication for methadone and its potential to precipitate hepatic encephalopathy; Hypersensitivity to methadone syrup or other ingredients in the formulation; Pregnancy; Severe chronic respiratory disease; Head injury and raised intracranial pressure: Respiratory depressant effects (with CO2 retention and secondary elevation of CSF pressure) may be markedly exaggerated in the presence of head injury, or a pre-existing increase in intracranial pressure. May produce effects that obscure the clinical course in participants with head injuries; Biliary tract disease: may cause constriction of sphincter of Oddi; Monoamine oxidase inhibitors use within 14 days of the study.

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **240**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Clinical Research Ethics Board (CREB) of University of

British Columbia (UBC)

Street address

Room 210, 828 West, 10th Avenue

City

Vancouver

Postal code

V5Z 1L8

Approval date

2015-05-11, 1394/02/21

Ethics committee reference number

H15-00220

Health conditions studied

1

Description of health condition studied

opioid dependence

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description

retention in treatment

Timepoint

3 months

Method of measurement

number (percentage of patients in the treatment)

Secondary outcomes

1

Description

Craving

Timepoint

Day 1-3/ Twice daily | Day 4-14/ Once daily | Day 15-28/
Three times a week | Day 29-84/ Once weekly

Method of measurement

VAS

2

Description

Withdrawal symptoms

Timepoint

Day 1-3/ Twice daily | Day 4-14/ Once daily | Day 15-28/
Three times a week | Day 29-84/ Once weekly

Method of measurement

subjective opiate withdrawal scale (SOWS)

3

Description

physical health

Timepoint

Baseline, month 1, 2 and 3

Method of measurement

Opiate treatment index (OTI)-health section

4**Description**

mental health

Timepoint

Baseline, month 1, 2 and 3

Method of measurement

Symptom Checklist 90 (SCL-90)

5**Description**

severity of substance use problem

Timepoint

Baseline, month 1, 2 and 3

Method of measurement

Addiction Severity Index

6**Description**

cognitive function

Timepoint

Baseline, month 1, 2 and 3

Method of measurement

Montreal Cognitive Assessment (MOCA)

7**Description**

quality of life

Timepoint

Baseline, month 1, 2 and 3

Method of measurement

WHOQOL-BREF

8**Description**

Client Satisfaction

Timepoint

month 3

Method of measurement

Treatment Perceptions Questionnaire (TPQ)

9**Description**

Abstinence

Timepoint

Baseline, month 1, 2 and 3

Method of measurement

self-report & urine toxicology

10**Description**

safety

Timepoint

Day 1-3/ Twice daily | Day 4-14/ Once daily | Day 15-28/
Three times a week | Day 29-84/ Once weekly

Method of measurement

Adverse Events Report Form

11**Description**

Cost- effectiveness

Timepoint

month 3

Method of measurement

QALY

Intervention groups**1****Description**

Intervention group: Opium with patient-centered flexible dosing in line with the national protocol published by Iranian Ministry of Health for maintenance treatment of opioid dependent population

Category

Treatment - Drugs

2**Description**

Active comparator: Methadone with patient-centered flexible dosing in line with the national protocol published by Iranian Ministry of Health for maintenance treatment of opioid dependent population

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Roozbeh substance use treatment clinic

Full name of responsible person

Afshar Amiri

Street address

Unit 3, 3rd floor, number 386, Dr. Gharib St.,
Keshavarz Blvd.

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Tehran University of
Medical Sciences

Street address

room 206, 1st floor, faculty of medicine, Tehran
University of Medical Sciences, Keshavarz Blvd.

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
University of British Columbia

Full name of responsible person
Michael Krausz

Position
MD, PhD, FRCPC

Other areas of specialty/work

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Full professor

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Person responsible for updating data

Contact

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Full name of responsible person
Sanam Javid

Position
MD

Other areas of specialty/work

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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