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

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Number 206, 1st floor, Administrative Bldg.,Tehran University of Medical Sciences, Keshavarz Boulvard, 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
Street address
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Person responsible for scientific inquiries

Contact
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Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh
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Person responsible for updating data

Contact
Name of organization / entity
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Sanam Javid
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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