Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Tramadol versus Methadone for the Management of Severe Heroin Withdrawal

Protocol summary

Summary
The objective of this randomized, triple-blind, placebo controlled study was to compare tramadol and methadone in the management of acute heroin withdrawal symptoms. Seventy heroin dependent outpatients received either methadone (60 mg/day) or tramadol (600 mg/day) for detoxification. Both drugs were continued for 3 days and then tapered 20% per 48 hours from initial dose. At the end of second week both drugs were discontinued. Severity of withdrawal symptoms was assessed five times at 4th, 6th, 8th, 10th, and 14th days by Objective Opioid Withdrawal Scale (OOWS). Side effects were also evaluated using checklist in each visit.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT138708261457N1**
Registration date: **2007-12-22, 1386/10/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2007-12-22, 1386/10/01

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source
Mazandaran University of Medical Sciences & Health Services

Expected recruitment start date
2007-12-22, 1386/10/01
Expected recruitment end date
2009-06-22, 1388/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Tramadol versus Methadone for the Management of Severe Heroin Withdrawal

Public title
Tramadol versus Methadone for the Management of Severe Heroin Withdrawal
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: DSM-IV-TR criteria for opioids dependence, current heroin dependence (i.e. withdrawal symptoms), age more than 18 years old Exclusion criteria: physical illness that needed tramadol and/or methadone consumption, using other substances except nicotine (other opioids, cannabinoids, alcohol and benzodiazepines etc.), major psychiatry disorders such as mood disorders (unipolar and bipolar), anxiety and psychotic disorders, major physical diseases such as hepatitis, tuberculosis, AIDS and so on, history of seizures

Age
From **18 years** old to **65 years** old
Gender
Male

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **70**
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
Ethics committee, Vice Chancellor for Research
Street address
Building No 2, Mazandaran University of Medical Sciences, Moallem Square, Sari, Mazandaran, IR Iran
City
Sari
Postal code
4817844718
Approval date
2007-12-11, 1386/09/20
Ethics committee reference number
86-59

Health conditions studied

1

Description of health condition studied
Heroin 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
management of heroin withdrawal
Timepoint
days 4, 6, 8, 10, 14
Method of measurement
Objective Opioid Withdrawal Scale (OOWS)

Secondary outcomes

1

Description
risk of respiratory depression
Timepoint
days 4, 6, 8, 10, 14
Method of measurement
physical examination and checklist

Intervention groups

1

Description
Methadone (60 mg/day) for 3 days and then the dose was gradually lowered (tapered 20% per 48 hours from the initial dose) until the end of 2nd week when it was discontinued
Category
Treatment - Drugs

2

Description
Tramadol (600 mg/day) for 3 days and then the dose was gradually lowered (tapered 20% per 48 hours from the initial dose) until the end of 2nd week when it 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

Mazandaran University of Medical Sciences
Full name of responsible person
Dr Seyed Jalal Hoseini Mehr
Street address
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
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

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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