

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of 0.125 and 0.250 mg of Naltrexone with Placebo in Decreasing Withdrawal Syndrome in Patients with Opium Addiction Referring to Addiction Treatment Clinic of Imam Reza (p) Hospital: A Clinical Trial

Protocol summary

Summary

Purpose: Evaluating the Effects of 0.125 and 0.250 mg of Naltrexone in Contrast to Placebo in Decreasing the Symptoms of Withdrawal Syndrome Design: Double-Blind Randomized Control Trial, Single Center, Trial Phase 2-3, Population: Opioid Dependent Subjects Referred to Addiction Treatment Clinic in Imam Reza (p) Hospital Inclusion: 18-65 Years Old Male Patients Exclusion: Patients with Cancer or Pain Syndrome Sample Size: 3 Groups of 21 Subjects Intervention: Evaluating the Effects of Adding 0.125 and 0.250 mg of Naltrexone in Reducing Symptoms of Withdrawal Syndrome Time: 10 Days After the Beginning of Detoxification Outcome: Reducing the Symptoms of Withdrawal Syndrome

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013081914404N1**
Registration date: **2013-11-04, 1392/08/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-11-04, 1392/08/13

Registrant information

Name

Majid Khadem-Rezaian

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research of Mashhad University of Medical Sciences

Expected recruitment start date

2013-09-16, 1392/06/25

Expected recruitment end date

2013-11-16, 1392/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of 0.125 and 0.250 mg of Naltrexone with Placebo in Decreasing Withdrawal Syndrome in Patients with Opium Addiction Referring to Addiction Treatment Clinic of Imam Reza (p) Hospital: A Clinical Trial

Public title

The Effects of Naltrexone in Opioid Detoxification

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Male patients who choose outpatient protocol for detoxification of opioids including opium, heroin, crack and tramadol ;filling the consent Exclusion Criteria: Cancer; Known pain syndrome; Diabetes

Age

From **18 years** old to **65 years** old

Gender

Male

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **63**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Ghoreishi Building, Before Golestan Crossroad,
Daneshgah Ave., Mashhad, Iran

City

Mashhad

Postal code

91375-345

Approval date

2010-09-25, 1389/07/03

Ethics committee reference number

88725

Health conditions studied

1

Description of health condition studied

opium addicted patients

ICD-10 code

F11

ICD-10 code description

Mental and behavioral disorders due to use of opioids

Primary outcomes

1

Description

clinical findings of withdrawal syndrome

Timepoint

1, 4 and 10 days after the beginning of study

Method of measurement

clinical examination by researcher

Secondary outcomes

empty

Intervention groups

1

Description

two Intervention groups treated with naltrexone made by researcher in very low dose of 0.125 and 0.250 mg used oral and daily for 10 days

Category

Treatment - Drugs

2

Description

Control group treated with sugar powder made by researcher used oral and daily for 10 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Addiction Treatment Clinic of Imam Reza (p) Hospital

Full name of responsible person

Dr. Reza Afshari

Street address

Addiction Treatment Clinic, Imam Reza (p) Hospital,
Ibn Sina Ave., Mashhad, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Mashhad University of Medical Sciences

Full name of responsible person

Dr. Ramezani

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of Mashhad 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**

Medical Toxicology Research Center of Mashhad
University of Medical Sciences

Full name of responsible person

Dr. Reza Afshari

Position

MD, Clinical Toxicologist, Associate Professor

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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

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Medical Toxicology Research Center of Mashhad
University of Medical Sciences

Full name of responsible person

Dr. Reza Afshari

Position

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