Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Pattern of Opioid Withdrawal Signs and Symptoms in Three Groups: 1. Patients undergoing Clonidine Abstinence Therapy, 2. Patients on starting clinical dose of Methadone Maintenance Therapy (MMT), and 3. Patients admitted for short-time detoxification with Methadone in Opioid Addict Subjects who were Referred to Imam-Reza Hospital Rehabilitation Center and Toxicology Ward – Mashhad from November 2008 to October 2009

Protocol summary

Summary

This randomized clinical trial study was designed to demonstrate the pattern of Opioid Withdrawal signs and symptoms in three groups. Each group contains 30 patients which makes a total patient of 90. The patients were selected from admitted patients in toxicology ward and referred to Rehabilitation Center of Imam-Reza Hospital. The patients will be randomly assigned to receive Clonidine Abstinence Therapy for 10 days, Methadone Maintenance Therapy (MMT) for 45 days, or short-time detoxification with Methadone for 5 days. The withdrawal signs and symptoms including Pain, nausea and vomiting, muscle twitching, rhinorrhea, yawning, diaphoresis, tremor, lacrimation, agitation, muscle aches, bone pain, arthralgia, piloerection, pupil size, abdominal pain, diarrhea, anxiety, dysphoric mood, etc. were compared between the three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706121187N1**
Registration date: **2010-01-09, 1388/10/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-01-09, 1388/10/19

Registrant information

Name

Reza Afshari

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2008-11-21, 1387/09/01

Expected recruitment end date

2009-11-21, 1388/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Pattern of Opioid Withdrawal Signs and Symptoms in Three Groups: 1. Patients undergoing Clonidine Abstinence Therapy, 2. Patients on starting clinical dose of Methadone Maintenance Therapy (MMT), and 3. Patients admitted for short-time detoxification with

Methadone in Opioid Addict Subjects who were Referred to Imam-Reza Hospital Rehabilitation Center and Toxicology Ward – Mashhad from November 2008 to October 2009

Public title
The Pattern of Opioid Withdrawal Signs and Symptoms in Three Groups
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: will to enter the study, Having no positive history of a psychological disorder, Not using any psychological either neurological drugs, Having no positive history of a cardiovascular disease, Being male, age between 18 to 60 years old Exclusion criteria: Discontinuing the treatment, Leaving the hospital sooner than the proper time
Age
From **18 years** old to **60 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences
Street address
Ghoreishi Building, Daneshgah Street, Mashhad, IRAN
City
Mashhad
Postal code
9138913131
Approval date
2008-01-19, 1386/10/29
Ethics committee reference number
6367

Health conditions studied

1

Description of health condition studied
Opioid Addiction
ICD-10 code
F11.3
ICD-10 code description
Mental and behavioural disorders due to use of opioids,withdrawal state

Primary outcomes

1

Description
less opioid withdrawal signs and symptoms
Timepoint
Daily
Method of measurement
The Pattern of Opioid Withdrawal Signs and Symptoms using Fultz chart

Secondary outcomes

empty

Intervention groups

1

Description
In the first group, patients are given Clonidine 0.1 mg per oral q 12 hours, Benzodiazepine (Chlorodiazepoxide 10mg at 6 Am, 10 mg at 2 Pm and 20 mg at 10 Pm per oral), Indomethacin 100 mg if necessary, Omeprazole 1 mg per oral before eating breakfast, Ibuprofen 400 mg q 12 hours per oral, with Risperidone 1 mg daily, and with or without Gabapentin and if needed Serum and Vitamin C in a 10 day period of time
Category
empty

2

Description
Patients on Methadone Maintenance Therapy (MMT) for 45 days, are given Methadone 40 mg per oral in the first day and then this dose will be increased 5 mg daily for disappearing the withdrawal signs and symptoms at most until the 10th day and then this dose will gradually be reduced to zero until the end of the 45 day period, pain killer (NSAIDs (Indomethacin 100 mg if necessary)) in the first ten days and also MOM syrup 10 cc q 8 hours per oral
Category
Treatment - Drugs

3

Description

The patients in the third group, are given Methadone 10 mg in the first day, 5 mg in the second and third day and nothing in the forth and fifth day, and also Maintenance serum of ⅓⅔ 2 Lit daily IV if necessary,Clonidine 0.1 mg per oral q 12 hours, Chlorodiazepoxide 10mg at 6 Am, 10 mg at 2 Pm and 20 mg at 10 Pm per oral, Indomethacin 100 mg if necessary, Omeprazole 1 mg per oral before eating breakfast, Ibuprofen 400 mg q 12 hours per oral, with Risperidone 1 mg daily

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

Toxicology ward, Medical Toxicology Research Center, Imam-Reza University Hospital

Full name of responsible person

Dr. Reza Afshari - Ali Javidi D B

Street address

Imam-Reza General Hospital - Mashhad - IRAN

City

Mashhad

2

Recruitment center

Name of recruitment center

Addiction Rehabilitation Clinic, Imam-Reza General Hospital, Mashhad

Full name of responsible person

Dr. Reza Afshari

Street address

Imam-Reza General Hospital - Mashhad - IRAN

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Jalil Tavakkol Afshari - Research Vice Chancellor of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Boo-ali research center,Boo-ali Square, Ferdowsi Square,Mashhad,IRAN

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Reza Afshari

Position

Assistant Professor of Toxicology in Mashhad University of Medical Sciences - MD, M.PH.,M.Sc.,Ph.D.

Other areas of specialty/work

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Position

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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