

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Study of the effects of a combination therapy of clonidine with dextromethorphan and/or amantadine on opium withdrawal syndrome compared with the single therapy of clonidine

Protocol summary

Summary

This study was performed as a double-blind randomized clinical trial in Health Ward in Razi Hospital, Tabriz, Iran. The sampling method was convenient and the subjects were selected among those admitted in Health Ward and addiction treatment and those who respected inclusion criteria, were randomly allocated in four groups of 30 subjects. The patients were subdivided into four groups. The first group received clonidine tablet 0.4-1.2 mg per day in three subdivided doses according to the patient's tolerance, clonazepam tablet one mg per eight hours, and acetaminophen tablet 500 mg every six hours. The second group received clonidine tablet 0.4-1.2 mg per day in three subdivided doses according to the patient's tolerance, clonazepam tablet one mg per eight hours, acetaminophen tablet 500 mg every six hours, and amantadine capsule 100 mg every 12 hours. The third group received clonidine tablet 0.4-1.2 mg per day in three subdivided doses according to the patient's tolerance, clonazepam tablet one mg per eight hours, acetaminophen tablet 500 mg every six hours, and dextromethorphan 75 mg every six hours. The fourth group received clonidine, clonazepam, amantadine and dextromethorphan with same doses. The treatment duration was regarded four days and all the patients were evaluated when admitted and also 24, 48, and 72 hours after it for severity of withdrawal symptoms. This evaluation was performed by physician and according to the Clinical Opiate Withdrawal Scale (COWS).

General information

Acronym

CCDAOW

IRCT registration information

IRCT registration number: **IRCT201207196972N2**

Registration date: **2012-08-30, 1391/06/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-30, 1391/06/09

Registrant information

Name

Ayyoub Malek

Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of research, Tabriz University of Medical Sciences

Expected recruitment start date

2011-06-07, 1390/03/17

Expected recruitment end date

2012-07-07, 1391/04/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effects of a combination therapy of clonidine with dextromethorphan and/or amantadine on opium

withdrawal syndrome compared with the single therapy of clonidine

Public title

The effects of a combination therapy of clonidine with dextromethorphan and/or amantadine on opium withdrawal syndrome compared with the single therapy of clonidine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Male sex; Aging from 20 to 40 years; Positive morphine test; Substance abuse diagnosis according to the DSM-IV-TR criteria. Exclusion criteria: The hepatic and renal diseases will evaluate according to the Creatinine and ALT measurements and if the subjects have levels higher than 1.2 mg/dl and 40 IU, respectively, will exclude; Also all patients will evaluate by clinical interview and the psychotic patients will exclude.

Age

From **20 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Research Vice Chancellor of Tabriz University of Medical Sciences

Street address

Golgasht - Tabriz University of Medical Sciences

City

Tabriz

Postal code

5167858564

Approval date

2010-01-24, 1388/11/04

Ethics committee reference number

5/4/7741

Health conditions studied

1

Description of health condition studied

Mental and behavioural disorders due to use of opioids

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description

Relieving the opioid withdrawal symptoms

Timepoint

Admission day, and 24, 48, and 72 hours later

Method of measurement

Clinical Opiate Withdrawal Scale

Secondary outcomes

empty

Intervention groups

1

Description

The first group will receive clonidine tablet 0.4-1.2 mg per day in three subdivided doses according to the patient's tolerance, clonazepam tablet one mg per eight hours and acetaminophen tablet 500 mg every six hours.

Category

Treatment - Drugs

2

Description

The second group will receive clonidine tablet 0.4-1.2 mg per day in three subdivided doses according to the patient's tolerance, clonazepam tablet one mg per eight hours, acetaminophen tablet 500 mg every six hours and amantadine capsule 100 mg every 12 hours.

Category

Treatment - Drugs

3

Description

The third group will receive clonidine tablet 0.4-1.2 mg per day in three subdivided doses according to the patient's tolerance, clonazepam tablet one mg per eight hours, acetaminophen tablet 500 mg every six hours, and dextromethorphan 75 mg every six hours.

Category

Treatment - Drugs

4

Description

The fourth group will receive clonidine tablet 0.4-1.2 mg per day in three subdivided doses according to the patient's tolerance, clonazepam tablet one mg per eight hours, amantadine capsule 100 mg every 12 hours and dextromethorphan 75 mg every six hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Ward in Razi Hospital

Full name of responsible person

Shahrokh Amiri

Street address

Razi Psychiatric Hospital, Elgoli Road

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice Chancellor of Tabriz University of Medical Sciences

Full name of responsible person

Dr.Rashidi

Street address

Tabriz University of Medical Sciences, Golgasht St

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Vice Chancellor of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Shahrokh Amiri

Position

Assistant Proffessor of Psychiatry,Tabriz University of Medical Sciences

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