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 dextromethorphane 75 mg every six hours. The fourth group received clonidine , clonazepam, amantadine and dextromethorphane 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

Country

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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 patientswill 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 Univercity of Medical Sciences

Street address
Golgasht -Tabriz Univercity 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 hour, and dextromethorphane 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 dextromethorphane 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
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Person responsible for updating data

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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