Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A placebo controlled double-blind add-on study of Ginseng on the opioid withdrawal syndrome

Protocol summary

Summary

We performed this randomized, double blind, placebo-controlled study to conclude a clinical data in human about the effects of Ginseng on opioid withdrawal symptoms. A total of 36 opioid dependent patients, all male, aged between 18 to 50 who met DSM-IV criteria for opioid dependence and started MMT protocol were randomly assigned to two groups of 18 to receive Ginseng (two 250 mg capsules daily) or placebo for first 15 days of detoxification. Patients were discharged from the study if they had positive urine tests indicating abuse of any drug and also if they missed more than one dose of Ginseng or a dose of methadone. Opioid withdrawal symptoms were measured by the COWS (clinical opioid withdrawal scale) on days 0, 1, 7, 10, 15. Also, the needed methadone dosage was counted everyday to be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009063106N4**
Registration date: **2010-11-29, 1389/09/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-11-29, 1389/09/08

Registrant information

Name
Farshad Hashemian
Name of organization / entity
Pharmaceutical Sciences Branch, Islamic Azad University (IAU)
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Recruitment status

Recruitment complete

Funding source

1.Goldaroo company 2. Pharmaceutical sciences branch of Islamic Azad university

Expected recruitment start date

2009-07-23, 1388/05/01

Expected recruitment end date

2010-04-21, 1389/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A placebo controlled double-blind add-on study of Ginseng on the opioid withdrawal syndrome

Public title

The effect of Ginseng augmentation on the intensity of opioid withdrawal symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Iinclusion criteria: -all patients were male abusing opioids for at least 1 year -age range was between 18 and 50. -all patients were at the beginning of induction phase of MMT protocol -subjects should not recieve any other medication which affects withdrawal symptoms. Exclusion criteria: -incidence of any allergic effect to ginseng or other ingredients of capsules -patient unlikely to continue the intervention -positive urine tests indicating abuse of any opioid or stimulant drug -missing

more than 1 dose of ginseng or a day of methadone treatment

Age
From **18 years** old to **50 years** old

Gender
Male

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Pharmaceutical science branch of Islamic azad university

Street address
No 99, Yasaman alley, Yakhchal St, Shariati Av

City
Tehran

Postal code

Approval date
2010-05-23, 1389/03/02

Ethics committee reference number
4115

Health conditions studied

1

Description of health condition studied
opioid withdrawal

ICD-10 code
F11

ICD-10 code description
Mental and behavioural disorders due to use of opioids / Dependence syndrome

Primary outcomes

1

Description
clinical opioid withdrawal symptoms

Timepoint
days 0,1,7,10,15

Method of measurement
clinical opioid withdrawal scale

Secondary outcomes

1

Description
methadone dosage

Timepoint
every day

Method of measurement
base on ducuments and patients records

Intervention groups

1

Description
drug group: patients recieved 250 mg oral capsule of ginseng twice daily for 15 days along with MMT protocol.

Category
Treatment - Drugs

2

Description
placebo group: patients recieved placebo oral capsule of gensing twice daily for 15 days along with MMT protocol.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Khane mehr clinic

Full name of responsible person
Dr Hamidreza Mokhberian

Street address
1008, between 1st and 2nd square of Sadeghie

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Pharmaceutical sciences branch of Islamic Azad university

Full name of responsible person
Dr. O. Dadras

Street address
No.99, Yasaman alley, Shariatee street
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Pharmaceutical sciences branch of Islamic Azad university
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Pharmaceutical science branch of Islamic azad university
Full name of responsible person
Dr. Farshad Hashemian
Position
Assisstani proffesor/clinical pharmasist
Other areas of specialty/work
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Web page address

Person responsible for updating data

Contact

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