Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of safety and efficacy of jadwar plant in improving the withdrawal symptoms of opioids: A triple blind trial Study

Protocol summary

Study aim
The aim of this study was to evaluate the effect of jadwar plant on quality of life and therapeutic indicators in patients deprived of opioid drugs.

Design
A randomized controlled clinical trial and triple blind, parallel study

Settings and conduct
This study is conducted at Shahid Beheshti Hospital in Qom.In this study 60 eligible patients who will be referred with opioid deprivation will be selected and will be randomly assigned to two groups of 30 people. Patients in the control group will receive the standard treatment regimen and placebo. Patients in the treatment group In addition to the standard regimen will be treated with 500 mg of jadwar capsules three times a day for 12 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria : all patients were abusing opioids for at least 1 year .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: any allergies to the active ingredient of the drug or side effects. Getting cancer

Intervention groups
Patient deprived of opioids are divided into two groups: jadwar capsules and placebo capsules.

Main outcome variables
The opiate withdrawal score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170112031893N7**
Registration date: **2020-06-18, 1399/03/29**
Registration timing: **prospective**
Last update: **2020-06-18, 1399/03/29**
Update count: **0**

Registration date
2020-06-18, 1399/03/29

Registrant information

Name
Hossein Yusefi

Name of organization / entity
Qom University of medical science

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date
2021-08-23, 1400/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of safety and efficacy of jadwar plant in improving the withdrawal symptoms of opioids: A triple blind trial Study

Public title
Evaluation of safety and efficacy of Jadwar plant in improving the withdrawal symptoms of opioids

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients were abusing opioids for at least 1 year All patients were at the beginning of induction phase of Methadone maintenance treatment protocol Subjects should not recieve any other medication which affects withdrawal symptoms

Exclusion criteria:

Any allergies to the active ingredient of the drug or side effects Getting Cancer

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be performed by random numbers generated by a computer (Stat Trek software). From list 1 to 60, this list is randomly divided between the two groups of jadwar and controls, and by considering the numbers, the two groups are randomized. Couples will be in the jadwar group and odd numbers will be in the placebo group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, patients, statistical analyst and physicians are not aware of the allocation of drugs and placebo, and someone outside the group is aware of the allocation of treatment.The placebo is a combination of starch with edible color that is similar to the jadwar capsule.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom University of Medical Sciences

Street address

Vice chancellor for research of Qom University of Medical Sciences, Safashar road, Qom, Iran

City

Qom

Province

Ghoum

Postal code

87366-37169

Approval date

2014-06-03, 1393/03/13

Ethics committee reference number

IR.MUQ.REC.1399.098

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

Opioid related disorders

Primary outcomes

1

Description

Opiate withdrawal syndrome score

Timepoint

Baseline, 4,8 and12 weeks after starting the medication

Method of measurement

Opiate withdrawal syndrome questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients receiving 500 mg capsules of Jadwar plant powder produced by Shefangar Company three times daily for three months

Category

Treatment - Drugs

2

Description

Control group: Patients receiving 500 mg capsules of placebo (Starch) produced by Shefangar Company three times daily for three months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Addiction treatment centers under the supervision of Qom University of Medical Sciences

Full name of responsible person
Masumeh Akbari

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Clinical Research Development Center, Shahid Beheshti Hospital, Shahid Beheshti Blvd, Azadegan Sq, Qom, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Ehsan Sharifipour

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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
Ghoum University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Hossein Yusefi

Position
Non-faculty

Latest degree
Bachelor

Other areas of specialty/work
Health Economy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available