

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 receive 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

Country

Iran (Islamic Republic of)

Phone

+98 25 3886 0146

Email address

driran1399@gmail.com

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 receive 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

Ghous

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 and 12 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

Street address

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

City

Qom

Province

Ghous

Postal code

3713649373

Phone

+98 25 3886 0146

Email

driran1399@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Ehsan Sharifipour

Street address

Number 83, Alley 4, Alley 1.1, Safashahr Street

City

Qom

Province

Ghous

Postal code

3716987366

Phone

+98 25 3285 4011

Email

driran1399@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ghous 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**

Ghous University of Medical Sciences

Full name of responsible person

Hossein Yusefi

Position

Non-faculty

Latest degree

Bachelor

Other areas of specialty/work

Health Economy

Street address

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

City

Qom

Province

Ghous

Postal code

3713649373

Phone

+98 25 3886 0146

Email

driran1390@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Ghous University of Medical Sciences

Full name of responsible person

Hossein Yusefi

Position

Non-faculty

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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

City

Qom

Province

Ghous

Postal code

3713649373

Phone

+98 25 3886 0146

Email

driran1390@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Ghous University of Medical Sciences

Full name of responsible person

Hossein Yusefi

Position

Non-faculty

Latest degree

Bachelor

Other areas of specialty/work

Health Economy

Street address

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

City

Qom

Province

Ghous

Postal code

3713649373

Phone

+98 25 3886 0146

Email

driran1390@yahoo.com

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