

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the effect of Barberry and Placebo on the symptoms of Turkish syndrome in patients undergoing methadone maintenance treatment

Protocol summary

Study aim

The purpose of this study is to reduce the daily dose of methadone to reduce its side effects and supplement barberry.

Design

This is a double-blind clinical trial (Phase 3) that is conducted on clients referring to addiction treatment centers in Sabzevar. Of the eligible individuals (obtaining informed consent, having complete vigilance and not taking another drug by the patient), 40 are selected (two groups of 20).

Settings and conduct

This study was performed on 40 patients referring to addiction treatment centers in Sabzevar, which are in the stage of stabilization of treatment (methadone and methadone dose on a weekly basis). The intervention group was treated with methadone syrup and barberry self-made capsules and the control group received methadone and placebo syrup for 2 months.

Participants/Inclusion and exclusion criteria

Getting informed consent and having full vigilance and no other drug use by the patient

Intervention groups

The intervention group was treated with methadone syrup and barberry self-made capsules and the control group received methadone and placebo syrup for 2 months.

Main outcome variables

Each week, variables: Renorrhea, muscle aches, appetite loss, obsession and diarrhea are recorded in the self-designed checklist.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170404033202N5**

Registration date: **2017-11-29, 1396/09/08**

Registration timing: **prospective**

Last update: **2017-11-29, 1396/09/08**

Update count: **0**

Registration date

2017-11-29, 1396/09/08

Registrant information

Name

Atefeh Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4422 9180

Email address

a.asadi.mm.1384@gmail.com

Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-07-22, 1397/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Barberry and Placebo on the symptoms of Turkish syndrome in patients undergoing

methadone maintenance treatment

Public title

Effect of Barberry on the symptoms of withdrawal syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Acquiring informed consent; Having full vigilance when completing the consent form; Accompanying a trusted person in the family

Exclusion criteria:

Existence of illness; The use of another drug by the patient

Age

From **60 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

The drug (powdered Barberry) and the medication in the capsules of the same type are packed in A and B.

Researcher and patients are not aware of the content, and then the data analysis will be presented to examine the outcome of the type A and B groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Sabzevar University of Medical Sciences

Street address

Central University, Asadabad Street

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Sabzevar

Province

Razavi Khorasan

Postal code

9617684155

Approval date

2017-12-22, 1396/10/01

Ethics committee reference number

IR.Medsab.Rec.1395.146

Health conditions studied**1****Description of health condition studied**

Addiction syndrome

ICD-10 code

f10-f11-f1

ICD-10 code description

Mental and behavioural disorders due to psychoactive substance use

Primary outcomes**1****Description**

Rhinorrhea

Timepoint

Every week up to 2 months

Method of measurement

Checklist

2**Description**

diarrhea

Timepoint

Every week up to 2 months

Method of measurement

Checklist

3**Description**

Reduce appetite

Timepoint

Every week up to 2 months

Method of measurement

Checklist

4**Description**

Dyspnea

Timepoint

Every week up to 2 months

Method of measurement

Visual Scale of Pain

5**Description**

Obsession

Timepoint

Every week up to 2 months

Method of measurement

Test Beck

Secondary outcomes

1

Description

Occupation

Timepoint

first

Method of measurement

chek List

2

Description

Age

Timepoint

first

Method of measurement

Birth certificate

3

Description

Sex

Timepoint

first

Method of measurement

male - female

Intervention groups

1

Description

Intervention group: During the 2 months of the study, methadone syrup and barberry cream capsules (250 mg of barberry dried extract of barberry powder were shed)

Category

Treatment - Drugs

2

Description

Control group: During the 2 months of the study, methadone and placebo syrup (color and size similar to barberry capsules) were treated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Addiction Clinic Behzist

Full name of responsible person

Atefeh Asadi

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Floor (-1), Deputy Medical Building, no. 15, Kashefialasl Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fereshteh GHorat

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Atefeh Asadi

Position

General Peractis

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Assistant Professor

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Specialist

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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available