

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of the effect of passiflora and piroxicam on the reduction of myalgia on the Patients requesting the leave of Methadone

Protocol summary

Study aim

The purpose of most effective least cost to reduce muscle pain caused by Opiate leave.

Design

This project is a one-stop clinical trial that will be carried out at the Centers for Addictive Disorders in Sabzevar County on 43 individuals who visit the facility (single-phase in Phase 3). Patients are randomly divided into two groups, 20 (control-B) and 23 (intervention group-A), randomly and in combination with codes A and B. The patients are randomly divided into two groups, 20 (control-B) and 23 patients (intervention group A).

Settings and conduct

This plan is a one-stop clinical trial (patients are not informed about the type of medicine, drugs are given as new capsules for the patient), which will be completed at the 43 patients who visit the center of Sabzevar's addiction treatment center. At the same time, with the onset of methadone, the control group, piroxicam, and the intervention group, will be prescribed a pumpkin drop, which should be consumed until the signs of withdrawal and stabilization of methadone dose are resolved

Participants/Inclusion and exclusion criteria

Individuals who enter into the design are logged in, and they should not use alcohol, glass or Druge Injectable .

Intervention groups

At the same time, with the onset of methadone, the control group, piroxicam, and the intervention group, will be prescribed a pumpkin drop, which should be consumed until the signs of withdrawal and stabilization of methadone dose are resolved. In the first days, 3rd, 6th and 9th treatments, the patient's vital signs, muscle pain (based on the visual scale of the pain) and anxiety (based on the test) will be recorded.

Main outcome variables

In the first days, 3rd, 6th and 9th treatments, the patient's vital signs, muscle pain (based on the visual scale of the pain) and anxiety (based on the test) will be

recorded.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170404033202N6**

Registration date: **2017-12-16, 1396/09/25**

Registration timing: **prospective**

Last update: **2017-12-16, 1396/09/25**

Update count: **0**

Registration date

2017-12-16, 1396/09/25

Registrant information

Name

Atefeh Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4422 9180

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Sabzevar University of Medical Sciences

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The comparison of the effect of passiflora and piroxicam on the reduction of myalgia on the Patients requesting the leave of Methadone

Public title
Investigation of the effect of passiflora on the reduction of myalgia after the withdrawal of drug addiction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 A quit candidate with methadone has personal satisfaction Age of more than 18 and less than 60 years old
Exclusion criteria:
 The visual score of pain is greater than 9 co-administration of sadation people with a history of injecting narcotic and scoliosis BMI> 30.

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **43**

Randomization (investigator's opinion)
Randomized

Randomization description
The envelopes containing the medication are identified as A and B, given randomly and in the same way to patients.

Blinding (investigator's opinion)
Single blinded

Blinding description
The envelopes containing the drug are identified as A and B, which the researcher does not know about envelopes. After the data is recorded by the researcher and the data analyst, the rows A and B will be reported to the researcher for the outcome.

Placebo
Not 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

Street address

Pardiss University, Kuosar Street, Toohid Blvd

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617684155

Approval date

2017-11-22, 1396/09/01

Ethics committee reference number

IR.Medsab.Rec.1395.146

Health conditions studied

1

Description of health condition studied

Musculoskeletal pain and anxiety after seeking addiction

ICD-10 code

f10-f11-f1

ICD-10 code description

Mental and behavioural disorders due to psychoactive substance use

Primary outcomes

1

Description

Muscular pain

Timepoint

In the first days, 3rd, 6th and 9th treatments

Method of measurement

Based on the visual scale of pain

2

Description

Anxiety

Timepoint

In the first days, 3rd, 6th and 9th treatments

Method of measurement

Beck Test

Secondary outcomes

1

Description

Sex

Timepoint

First

Method of measurement

2**Description**

age

Timepoint

first

Method of measurement

Identity Card

Intervention groups**1****Description**

Intervention group: At the same time, with the onset of methadone, the intervention group will be prescribed a dropsy pumpkin that should be used until the signs of withdrawal and stabilization of the dose of methadone are consumed.

Category

Treatment - Drugs

2**Description**

Control group: At the same time, with the onset of methadone, the control group will be prescribed piroxicam which should be used until the symptoms of withdrawal and stabilization of the dose of methadone are consumed.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Behzist addiction Clinic

Full name of responsible person

Atefeh Asadi

Street address

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

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+98 51 4422 4519

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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

Mohammad Nematshahi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Nematshahi

Position

Assistant Professor

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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

No - There is not 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