

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Evaluation of the effect of oral administration of Naloxone on bowel habit in patients on methadone maintenance therapy

#### Protocol summary

##### Study aim

Evaluation of the effect of oral administration of Naloxone on bowel habit in patients on methadone maintenance therapy

##### Design

A randomized, double blind placebo control, Superiority, parallel groups, clinical trial on 80 precipitants. The blinded therapists of Harm Reduction Centers delivers 15 capsules to every patient and assesses the current situations and their outcomes.

##### Settings and conduct

the study will conduct in 4 Harm Reduction Centers of Mashhad . The blinded therapists of HRCs delivers 15 capsules to every patient and assesses the current situations and their outcomes

##### Participants/Inclusion and exclusion criteria

Participant in the MMT( <75 mg /day) program for at least three months. they will exclude if they have : Past history of GI surgery (Except Appendectomy), Thyroid disease, diabetes mellitus. Hypercalcemia, renal failure, using Tricyclic antidepressant, Using Calcium Chanel blockers Hypertension, cardiac disease, Multi-drugs abuser, Using anticholinergic drugs, Pregnancy, Recently weight loss More then 4, NVD or Past history of Severe labor and Parkinsonism.

##### Intervention groups

80 methadone maintenance treated precipitants will divide to 4 groups who receive 0,0.5,2 or 4 mg/day oral naloxane capsules. The previous laxative treatment will continue.

##### Main outcome variables

Constipation score; Withdrawal scoring.; total amounts of laxative use in past 2 weeks

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190207042648N2**

Registration date: **2020-08-01, 1399/05/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-08-01, 1399/05/11**

Update count: **0**

##### Registration date

2020-08-01, 1399/05/11

##### Registrant information

###### Name

Mohammad Moshiri

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3878 2615

###### Email address

moshirimo@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-22, 1399/05/01

##### Expected recruitment end date

2021-07-23, 1400/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of oral administration of Naloxone on bowel habit in patients on methadone maintenance therapy

##### Public title

The effect of oral Naloxone on Methadone induced constipation

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Participant in the MMT program for at least three months  
Willingness to participate in research studies  
Receive methadone less than 75 mg /day

##### **Exclusion criteria:**

Past history of GI surgery (Except Appendectomy)  
History of Thyroid disease  
History of diabetes mellitus.  
Hypercalcemia renal failure using Tricyclic antidepressant  
Using Calcium Channel blockers  
Hypertension cardiac disease  
Multi-drugs abuser  
Using anticholinergic drugs  
Pregnancy  
Recently weight loss  
More than 4 NVD or Past history of Severe labor  
Parkinsonism

#### **Age**

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

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

- Participant
- Care provider

#### **Sample size**

Target sample size: **80**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

The participants will be divided 4 groups by simple individual randomization method. When a patients referred to clinic will be divided into 4 groups by sealed envelopes.

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

The participants will be blinded about the treatment. Researcher tells them " you will treat by a Naloxane capsule ( various doses) or Placebo". The evaluators ( Physicians of clinics) will be blinded on the groups treatment. Others (researcher, analyzer and person responsible for patient care) know the groups.

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

In this study 3 doses of Naloxone were compared by placebo.

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

###### **Street address**

Gharashi building, Danshghah street.

###### **City**

Mashhad

###### **Province**

Razavi Khorasan

###### **Postal code**

9177899191

##### **Approval date**

2019-07-06, 1398/04/15

##### **Ethics committee reference number**

IR.MUMS.REC.1398.128

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Drug induced constipation

##### **ICD-10 code**

K59.0

##### **ICD-10 code description**

Constipation

### **Primary outcomes**

#### **1**

##### **Description**

Constipation score

##### **Timepoint**

At start, one and two weeks later (end of research)

##### **Method of measurement**

Constipation Scoring System and Bristol scoring

#### **2**

##### **Description**

Defecation in the three areas of abdominal, rectal and feces

##### **Timepoint**

At start , one and two weeks later ( end of research)

##### **Method of measurement**

PAC-SYM questionnaire

### **Secondary outcomes**

#### **1**

##### **Description**

constipation scoring

##### **Timepoint**

At start , one and two weeks later ( end of research)

##### **Method of measurement**

PAC-SYM questionnaire and Constipation Scoring System

## 2

### **Description**

Opiate withdrawal scoring

### **Timepoint**

One and two weeks later ( end of research)

### **Method of measurement**

opiate withdrawal scale

## **Intervention groups**

### 1

### **Description**

Intervention group:they will be treated by oral naloxane capsules ( 0.5 or 2 or 4 mg/day) .Also, they will be treated by their previous laxative medication without change.

### **Category**

Treatment - Drugs

### 2

### **Description**

Control group: they will be treated by their previous laxative medication without change. They will receive placebo.

### **Category**

Placebo

## **Recruitment centers**

### 1

### **Recruitment center**

#### **Name of recruitment center**

4 hazard reduction clinics of Mashhad city /Iran

#### **Full name of responsible person**

Mohammad Moshiri

#### **Street address**

Ēbnesina Street, Emam Reza Hospital, Clinical toxicology department.

#### **City**

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#### **Province**

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#### **Postal code**

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#### **Phone**

+98 51 3802 2515

#### **Fax**

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#### **Email**

moshirimo@gmail.com

## **Sponsors / Funding sources**

### 1

### **Sponsor**

#### **Name of organization / entity**

Mashhad University of Medical Sciences

### **Full name of responsible person**

Dr. Mohsen Tafagodi

### **Street address**

Central office of Mashhad University of Medical Sciences, Daneshgah Ave.

### **City**

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### **Province**

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### **Phone**

+98 51 3841 2081

### **Fax**

+98 51 3843 0249

### **Email**

vcresearch@mums.ac.ir

### **Web page address**

<http://v-research.mums.ac.ir/index.php/component/content/article/62-vcresearch/514-tell>

### **Grant name**

### **Grant code / Reference number**

### **Is the source of funding the same sponsor organization/entity?**

Yes

### **Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

#### **Full name of responsible person**

Dr Mohammad Moshiri

#### **Position**

Assistant professor

#### **Latest degree**

Ph.D.

#### **Other areas of specialty/work**

Toxicology

#### **Street address**

Department of clinical toxicology , Emam Reza hospital, Ebnesina Avenue, Mashhad Iran

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Toxicology

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## Person responsible for updating data

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Mashhad University of Medical Sciences

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Mohammad Moshiri

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Associate professor

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information.

**Study Protocol**

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

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

No - There is not a plan to make this available