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 trail 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
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Iran (Islamic Republic of)
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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 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 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 envelops.

Blinding (investigator's opinion)

Double blinded

Blinding description

The precipitants 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.

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Razavi Khorasan

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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 Briston 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
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Ebnesina Street, Emam Reza Hospital, Clinical toxicology department.
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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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