Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Double-blind placebo-controlled randomized clinical trial on the use of oral naloxone on constipation of patients treated by opium tincture

Protocol summary

Study aim

Evaluation of the effect of oral administration of Naloxone on opium induced constipation of patients treated by opium tincture maintenance therapy

Design

A double-blind clinical trial study with placebo. The sample size is 120 people (40 people in each group). The blinded therapist delivers the capsules to each patient and assesses the current situations and their outcomes. . Others of the research team (researcher, analyzer and person responsible for patient care) know which patients receive which treatment.

Settings and conduct

The study will conduct in 2 Harm Reduction Centers of Mashhad . The blinded therapists of HRCs delivers 7 coded capsules after initial evaluation (for seven days). The researcher will call to the participants next day to evaluate intolerable opiate withdrawal syndrome. If it is happen, the patient will be excluded. Others will be evaluated at the end of the first week and re-treated for one week again. They will also be evaluated at the end of research.

Participants/Inclusion and exclusion criteria

The participants that are in the opium tincture treatment (less than 10 ml per day) in the 5 first months and had 20 to 50 years old. They will exclude if they have any physically condition could precipitate constipation (see exclusion criteria)

Intervention groups

One hundred twenty patients treated with opium syrup will be divided into three groups of placebo recipients and recipients of 2 and 4 mg oral naloxone doses daily for two weeks. None of the patients discontinued their previous treatments.

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: **IRCT20190207042648N3**
Registration date: **2021-02-16, 1399/11/28**
Registration timing: **prospective**

Last update: **2021-02-16, 1399/11/28**
Update count: **0**

Registration date

2021-02-16, 1399/11/28

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

2021-05-22, 1400/03/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double-blind placebo-controlled randomized clinical trial on the use of oral naloxone on constipation of patients treated by opium tincture

Public title
Effect of oral naloxone on constipation of patients treated by opium tincture

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Participants that are in the opium tincture treatment in the 5 first months. Willingness to participate in research studies. Receiving the average dose of the opium tincture less than 10 CC in the last month. Age between 20 - 50 years.

Exclusion criteria:
Past history of GI surgery History of Thyroid disease History of Diabetes Hypercalcemia Renal failure Using Tricyclic antidepressant Using Calcium Chanel blockers Hypertension Cardiac disease Multi-drugs abuser Using anticholinergic drugs Pregnancy Recently sever weight loss more than 4 NVD or past history of severe labor Parkinsonism

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be divided3 groups by simple individual randomization method. When a patients referred to clinic will be divided into 3 groups by sealed envelops. Physician will treat precipitants according the code in envelope

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient will be informed that he or she will be given medication or a placebo. Primary Assessors and Consequences (Clinic Physician) are unaware of which patient is receiving what treatment and will evaluate the patient regardless of treatment. Others of the research team know which patients receive which treatment . All drugs that are delivered to patients are in the form of packages with the code and the form of drugs is the same (the drug does not have a specific smell or taste).

Placebo
Used

Assignment
Parallel

Other design features
In this study 2 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
2020-10-27, 1399/08/06

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.609

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

Method of measurement
PAC-SYM questionnaire

Secondary outcomes

1

Description
Opiate withdrawal scoring
Timepoint
24 hours after starting the treatment patients were evaluated by phone call. One and two weeks later (end of research) were scored
Method of measurement
opiate withdrawal scale

Intervention groups

1

Description
Intervention group 1: The blinded therapists of HRCs delivers 7 coded capsules contain 2 mg Naloxan (Sigma) after initial evaluation (for seven days). The capsuled were filled by faculty of pharmacy of MUMS . The researcher will call to the participants next day to evaluate intolerable opiate withdrawal syndrome. If it is happen, the patient will be excluded. Others will be evaluated at the end of the first week and re-treated for one week again. They will also be evaluated at the end of research. The patients can use their lubricant medications if they need.
Category
Treatment - Drugs

2

Description
Intervention group2: The blinded therapists of HRCs delivers 7 coded capsules contain 4 mg Naloxan (Sigma) after initial evaluation (for seven days). The capsuled were filled by faculty of pharmacy of MUMS . The researcher will call to the participants next day to evaluate intolerable opiate withdrawal syndrome. If it is happen, the patient will be excluded. Others will be evaluated at the end of the first week and re-treated for one week again. They will also be evaluated at the end of research. The patients can use their lubricant medications if they need.
Category
Treatment - Drugs

3

Description
Control group:: The blinded therapists of HRCs delivers 7 coded capsules contain placebo after initial evaluation (for seven days). The capsuled were filled by faculty of pharmacy of MUMS . The researcher will call to the participants next day to evaluate intolerable opiate withdrawal syndrome. If it is happen, the patient will be excluded. Others will be evaluated at the end of the first week and re-treated for one week again. They will also be evaluated at the end of research. The patients can use their lubricant medications if they need.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
East educational research center of drug abuse and addictive behavior
Full name of responsible person
Hamid Reza Fathi
Street address
No 135, Soroosh 8 Ave, Vakil Abad Blvd, mashhad town
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2

Recruitment center
Name of recruitment center
Ebn'e Sina Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Research chancellery of Mashad University of Medical Science, Daneshgah Ave, Mashhad. Iran
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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
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
Mohammad Moshiri

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Toxicology

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Person responsible for updating data

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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

Not applicable