

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Effect of magnesium sulfate on induced opiate- withdrawal syndrome

#### Protocol summary

##### Study aim

Effect of magnesium sulfate on induced opiate-withdrawal syndrome

##### Design

A randomized, double blind, placebo controlled clinical trial with a parallel group design of 40 patients with induced opiate withdrawal syndrome . Treatment group will receive MgSo4 in addition of usual recommended treatment (clonidine, Benzodiazepine , Apotel)

##### Settings and conduct

We compare the opiate withdrawal score at 0, 0.5 and 2 hours on both groups o patients were reffed to Emam Reza Hospital of Mashhad We also record the total doses of administrated drugs (clonidine, Benzodiazepine ), demographic variables and some confusing variables such as: kind and doses of antagonist, history of drug use (duration, type and the last dose), the time interval between use of antagonist or partial agonists and start of treatment.

##### Participants/Inclusion and exclusion criteria

All patient with Induced opiate withdrawal syndrome  
exclusion criteria: Naloxane treated, Ischemic heart disease, renal failure, hepatic failure, uncontrolled hypertension, Patients with long-term treatment with calcium receptor antagonists,allergy to magnesium compounds, Patients who have a history of concomitant use of other substances such as methamphetamine, alcohol or other stimulants , Patients with asthma, patients with Diabetic neuropathy, In case of incomplete registration ,Lack of patient collaboration and patient inaccessibility (in providing required information)

##### Intervention groups

Treatment group , Will be treated by 3 gram MgSo4 through 20 minutes intravenously that will be continued by 10 mg/kg/hours MgSo4 up to appropriate response or 3 hours

##### Main outcome variables

The opiate withdrawal score ; total doses of administrated drugs (clonidine, Benzodiazepine ).

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190207042648N1**

Registration date: **2019-05-22, 1398/03/01**

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

Last update: **2019-05-22, 1398/03/01**

Update count: **0**

##### Registration date

2019-05-22, 1398/03/01

##### 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

2019-03-21, 1398/01/01

##### Expected recruitment end date

2020-03-20, 1399/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of magnesium sulfate on induced opiate-

withdrawal syndrome

### Public title

Effect of magnesium sulfate on induced opiate-withdrawal syndrome

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

patients with Induced opiate withdrawal syndrome

#### Exclusion criteria:

Naloxane induced withdrawal Ischemic heart disease renal failure Hepatic failure Uncontrolled hypertension. AIDS Cerebrovascular disease long-term treatment with calcium Chanel blocker Diabetic neuropathy. Allergy to magnesium compounds Concomitant use of other substances such as methamphetamine, alcohol or other stimulants Asthma. In case of incomplete registration ,Lack of patient collaboration and patient inaccessibility (in providing required information) Pregnancy

### Age

From **14 years** old to **40 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Outcome assessor

### Sample size

Target sample size: **40**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The participants will be divided two groups by simple individual randomization method . When a patients referred to ED will be divided into 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 infusion of MgSO4 or normal saline". The evaluators 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

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

### Street address

Ghorash bulding, Danshghah street,

### City

Mashhad

### Province

Razavi Khorasan

### Postal code

9177899191

### Approval date

2019-04-07, 1398/01/18

### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.012

## Health conditions studied

### 1

#### Description of health condition studied

withdrawal of opiate

#### ICD-10 code

F11.3

#### ICD-10 code description

Mental and behavioural disorders due to use of opioids withdrawal state

## Primary outcomes

### 1

#### Description

Opiate withdrawal score

#### Timepoint

at start and 0.5 and 2 hours after treatment

#### Method of measurement

By Opiate withdrawal scale

### 2

#### Description

MG serum level

#### Timepoint

start and after 2 hours

#### Method of measurement

MG serum level

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: patients with induced opiate withdrawal. they will treated by magnesium sulfate 3gr Iv Infusion in 20 min stat & 10 mg/kg/h Iv Infusion for 3 hours in addition standard therapy.

#### Category

Treatment - Drugs

**2**

### Description

Control group: patients with induced opiate withdrawal. they receive Tab clonidine 0.2 mg q1h up to 0.8 mg if SBP> 100 mmhg / Amp Diazepam 10 mg q15 min IV slowly up to 30 mg /Amp Apotel 1gr Iv in 200 cc serum N/s in 20 min

### Category

Treatment - Drugs

## Recruitment centers

**1**

### Recruitment center

#### Name of recruitment center

اورژانس مسمومين بيمارستان امام رضا مشهد

#### Full name of responsible person

Mohammad Moshiri

#### Street address

Ebnesina street

#### City

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#### Postal code

9137913316

#### Phone

+98 51 3854 3031

#### 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

Mohsen Tafagodi

#### Street address

Daneshgah street Ghorashi building

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9137913316

#### Phone

+98 51 3841 1538

#### Fax

+98 51 3841 1538

#### Email

vcresearch@mums.ac.ir

#### Web page address

<http://v-research.mums.ac.ir/index.php/component/co>

ntent/article/62-vcresearch/514-tell

### Grant name

Dr Mohsen Ebrahimi

### Grant code / Reference number

970572

### 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

Associate professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Toxicology

#### Street address

Ebnesina Street , Emam Reza Hospital , Clinical toxicology department

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Mohammad Moshiri

#### Position

Associate professor

#### Latest degree

Ph.D.

**Other areas of specialty/work**

Toxicology

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**Email**

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**Person responsible for updating data**

**Contact**

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Mashhad University of Medical Sciences

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**Position**

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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**

security of participants

**Study Protocol**

Yes - There is 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**

No - There is not 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

**Title and more details about the data/document**

protocol of research

**When the data will become available and for how long**

from now

**To whom data/document is available**

every researchers

**Under which criteria data/document could be used**

For research and treatment proposes

**From where data/document is obtainable**

Mohammad Moshiri

**What processes are involved for a request to access data/document**

send a email to correspond and introduce the proposes and team

**Comments**