

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

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Ebnesina street

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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

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+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

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Ebnesina Street , Emam Reza Hospital , Clinical toxicology department

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Person responsible for scientific inquiries

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Position

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Other areas of specialty/work

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Person responsible for updating data

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

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