

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of intravenous fat emulsion 20% infusion in controlling adverse effects of methadone toxicity in admitted patients

Protocol summary

Study aim

Evaluation of the effect of intravenous fat emulsion 20% infusion in controlling adverse effects of methadone toxicity in admitted patients

Design

This blind side clinical trial will be performed on 82 patients. The random number table method will be used to randomize and divide patients into two intervention and control groups.

Settings and conduct

This clinical trial will be performed in the poisoned ward of Imam Reza Hospital. A total of 82 patients over the age of 18 will be randomly admitted to the two intervention and control groups after obtaining informed consent. In addition to the standard treatment (naloxone), 41 patients admitted to the intervention group will receive a 20% intravenous fat emulsion at a dose of 1.5 ml / kg as an intravenous infusion over 60 minutes. 41 patients admitted to the control group will receive standard treatment. At the end of the intervention, measurable primary and secondary outcomes will be monitored according to a specific schedule.

Participants/Inclusion and exclusion criteria

History of pancreatitis with hyperlipidemia Known allergies eggs or soy proteins History of severe hyperlipidemia (serum triglyceride concentration greater than 1000 mg / dl) Acute shock History of severe hepatic impairment (child pugh class C) Acute heart attack Non-opioid poisoning Cerebrovascular events Taking other drugs that increase the QT interval

Intervention groups

Intervention group: In the intervention group, in addition to the standard treatment (naloxone), patients will receive a 20% intravenous fat emulsion at a dose of 1.5 ml / kg as an intravenous infusion over 60 minutes. Control group: Patients admitted to the control group will receive standard treatment.

Main outcome variables

Number of breaths per minute

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201220049774N2**

Registration date: **2022-01-19, 1400/10/29**

Registration timing: **prospective**

Last update: **2022-01-19, 1400/10/29**

Update count: **0**

Registration date

2022-01-19, 1400/10/29

Registrant information

Name

Hesamoddin Hosseinjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 1586

Email address

hosseinjanih@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-30, 1400/11/10

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of intravenous fat emulsion 20% infusion in controlling adverse effects of methadone toxicity in admitted patients

Public title

Effect of intra-lipid in methadone toxicity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Giving informed consent

Exclusion criteria:

History of pancreatitis with hyperlipidemia Known allergies eggs or soy proteins History of severe hyperlipidemia (serum triglyceride concentration greater than 1000 mg / dl) Acute shock History of severe hepatic impairment (child pugh class C) Acute heart attack Non-opioid poisoning Cerebrovascular events Taking other drugs that increase the QT interval

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the method of randomization is simple in "www.randomization.com" sight.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, only participants were blinded of therapeutic type.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashad university of medical sciences

Street address

Department of clinical pharmacy, faculty of pharmacy, Ferdowsy university of campus, Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9117969173

Approval date

2022-01-01, 1400/10/11

Ethics committee reference number

IR.MUMS.REC.1400.291

Health conditions studied

1

Description of health condition studied

Poisoning by narcotics and psychodysleptics [hallucinogens]: Methadone

ICD-10 code

T40.3

ICD-10 code description

Poisoning by, adverse effect of and underdosing of methadone

Primary outcomes

1

Description

Number of breaths per minute

Timepoint

From before intervention to 5 hours after it per one hour

Method of measurement

Cardiac monitoring device

Secondary outcomes

1

Description

QT intervale

Timepoint

From before intervention to 5 hours after it hourly

Method of measurement

Cardiac monitoring device

2

Description

systolic, diastolic and mean arterial blood pressure

Timepoint

From before intervention to 5 hours after it hourly

Method of measurement

Cardiac monitoring device

3

Description

Shortness of breath, cyanosis and pupil size

Timepoint

From before intervention to 5 hours after it hourly

Method of measurement

Physical examination

4

Description

blood oxygen concentration level

Timepoint

From before intervention to 5 hours after it hourly

Method of measurement

Cardiac monitoring device

5

Description

level of consciousness

Timepoint

From before intervention to 5 hours after it hourly

Method of measurement

Glasgow coma scale

6

Description

Heart rate

Timepoint

From before intervention to 5 hours after it hourly

Method of measurement

Cardiac monitoring device

7

Description

Number of times naloxone is prescribed

Timepoint

5 hours after intervention

Method of measurement

Patient nursing care cardex

Intervention groups

1

Description

Intervention group: In the intervention group, in addition to the standard treatment (naloxone), patients will receive a 20% intravenous fat emulsion at a dose of 1.5 ml / kg as an intravenous infusion over 60 minutes.

Category

Treatment - Drugs

2

Description

Control group: Patients admitted to the control group will receive standard treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Hesamoddin Hosseinjani

Street address

Imam Reza Educational, Research and Treatment Center, Imam Reza Square, Ibn-e Sina Avenue

City

Mashad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2717

Fax

+98 51 3802 2717

Email

IRH@mums.ac.ir

Web page address

<https://emamreza.mums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology

Street address

University Street, next to Hoveyze Cinema, Ghoreshi Building, Deputy of Research and Technology

City

Mashad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Fax

+98 51 3843 0249

Email

vcresraech@mums.ac.ir

Web page address

<https://v-research.mums.ac.ir/>

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

Razavi Khorasan
Postal code
9177948954
Phone
+98 51 3180 1586
Email
hosseinjanih@mums.ac.ir

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hesamoddin Hosseinjani
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Medical Pharmacy
Street address
Department of Clinical Pharmacy, Faculty of
Pharmacy, Ferdowsi University Campus, Azadi
Square, Mashhad
City
Mashad
Province
Razavi Khorasan
Postal code
9177948954
Phone
+98 51 3180 1586
Email
hosseinjanih@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hesamoddin Hosseinjani
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Medical Pharmacy
Street address
Department of Clinical Pharmacy, Faculty of
Pharmacy, Ferdowsi University Campus, Azadi
Square, Mashhad
City
Mashad
Province

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hesamoddin Hosseinjani
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Medical Pharmacy
Street address
Department of Clinical Pharmacy, Faculty of
Pharmacy, Ferdowsi University Campus, Azadi
Square, Mashhad
City
Mashad
Province
Razavi Khorasan
Postal code
9177948954
Phone
+98 51 3180 1586
Email
hosseinjanih@mums.ac.ir

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 more information

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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