Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 squre
City
Mashhad
Province
Razavi Khorasan
Postal code
۹۱۷۷۹۶۹۱۷۳
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
Glosgow 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 Hoveyzeh 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

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

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