

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of Intravenous fat emulsion (Intralipid) in treatment of acute tramadol poisoning

Protocol summary

Summary

In the present study, the effects of intravenous administration of intralipid in treatment of acute tramadol poisoning will be assessed. The patients in case group will be received a vial of intralipid 20% upon arrival to the hospital. The patients in control group will not received it. Both groups will be undertaken other standard management included GI decontamination, supportive measures, and therapy for possible convulsion. the groups will be compared for the severity and/or duration of clinical and lab symptoms and signs, and duration of hospital admission.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050120951N3**
Registration date: **2017-05-29, 1396/03/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-29, 1396/03/08

Registrant information

Name

Amir Mohammad Kazemifar

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3335 6696

Email address

amkazemifar@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

The Research Office of Qazvin's Faculty of Medicine

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Intravenous fat emulsion (Intralipid) in treatment of acute tramadol poisoning

Public title

Intralipid in treatment of tramadol poisoning

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: history of tramadol poisoning, presence of pertinent clinical signs and symptoms, consent for participation in the study
Exclusion: co-ingestion, history of hypersensitivity to the drug, presence of a major internal disease

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin's University of Medical Sciences

Street address

Bahonar Bolvd.

City

Qazvn

Postal code

Approval date

2017-02-11, 1395/11/23

Ethics committee reference number

28/20/13399

Health conditions studied

1

Description of health condition studied

Acute tramadol poisoning

ICD-10 code

T40

ICD-10 code description

Poisoning by narcotics and psychodysleptics
[hallucinogens]

Primary outcomes

1

Description

convulsion

Timepoint

at the time of admission and during hospital stay

Method of measurement

observation by nurse or physician

2

Description

duration of hospitalization

Timepoint

at the time of discharge

Method of measurement

according to the hospital records

Secondary outcomes

1

Description

systolic blood pressure

Timepoint

during hospital admission

Method of measurement

sphygmomanimeter

2

Description

diastolic blood pressure

Timepoint

during hospital admission

Method of measurement

sphygmomanimeter

3

Description

heart rate

Timepoint

during hospital admission

Method of measurement

by nurse or physician

4

Description

serum CPK level

Timepoint

at the time of admission and 24 hours later

Method of measurement

by lab

Intervention groups

1

Description

case group: Intralipid 20% 500 cc infusion in 1-2 hours

Category

Treatment - Drugs

2

Description

control group: no drug

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Buali hospital

Full name of responsible person

Abbas Bedram
Street address
City
Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Mjanaz Abbasi
Street address
Bahonar Blvd
City
Qazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of medical Sciences
Full name of responsible person
Amir Mohammad Kazemifar
Position
faculty member
Other areas of specialty/work
Street address
Buali hospital
City
Qazvin
Postal code
Phone
+98 28 3333 2930
Fax
Email
amkazemifar@qums.ac.ir
Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Amir Mohammad Kazemifar
Position
Faculty member
Other areas of specialty/work
Street address
Buali hospital
City
Qazvin
Postal code
Phone
+98 28 3333 2930
Fax
Email
amkazemifar@qums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Amir Mohammad Kazemifar
Position
Faculty member
Other areas of specialty/work
Street address
Buali hospital
City
Qazvin
Postal code
Phone
+98 28 3333 2930
Fax
Email
amkazemifar@qums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty