Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 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. Te 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 poioiiong

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
sphygnomanimeter

2

Description
diastolic blood pressure
Timepoint
during hospital admission
Method of measurement
sphygnomanimeter

3

Description
heart rate
Timepoint
during hospital admission
Method of measurement
by nurse or phycician

4

Description
serum CPK level
Timepoint
at he 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