Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Role of Administration of IV IntraLipid in Level Of Consciousness in coma Poisoned Patients Referred to Emergency Service of Yaft Abad Hospital during october 2010 to March 2011

Protocol summary

Summary

The main purpose of this study is the evaluation of Intralipid prescribed in coma patients to enhance the level of consciousness. A total of 100 poisoned patients with GCS equal to or less than eight was admitted to Shohadaye Yaftabad hospital of Tehran from October 2010 to March 2011, will be randomly assigned in to the intervention group (50 patients, received 20 CC / kg of 10% intralipid alongside routine treatment) or control group (50 patients, routine treatments performed). 30 minutes after the intalipid administration, trained individuals will examine changes in primary outcome measure (level of consciousness) and secondary outcome measures including vital signs (number of respiration, pulse rate, temperature and blood pressure), EKG changes, Arterial Blood Gas and biochemical experiments (Urea, Cratinine, Sugar, NA and K of blood).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010134925N1**
Registration date: **2010-11-12, 1389/08/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-11-12, 1389/08/21

Registrant information

Name

Bahareh Sepehrian

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 6668 3290

Email address

b.sepehrian@stu.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Role of Administration of IV IntraLipid in Level Of Consciousness in coma Poisoned Patients Referred to Emergency Service of Yaft Abad Hospital during october 2010 to March 2011

Public title

The Role of Administration of IV IntraLipid in Level Of Consciousness in coma Poisoned Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: GCS less than 8 Exclusion criteria: Presence of specific antidote (such as naloxone)

Age

No age limit

Gender

Both

Phase
N/A
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
Iran University of Medical Science and health services
Street address
between Chamran and Sheykh Fazlollahe Nuri expresseay, Shahid Hemmat Expressway
City
Tehran
Postal code
Approval date
2010-10-10, 1389/07/18
Ethics committee reference number
895/9

Health conditions studied

1

Description of health condition studied
drug poisoning
ICD-10 code
S00, T98
ICD-10 code description
Injury, poisoning and certain other consequences of external causes

Primary outcomes

1

Description
GCS
Timepoint
Before Intralipid prescription and 30 minutes after drug usage
Method of measurement
Based on physical examination by a trained person and based on the specific scoring method for this criteria(up to six for movement response, five for language response, four for the eye response)

Secondary outcomes

1

Description
ABG
Timepoint
Before Intralipid prescription and 30 minutes after drug usage
Method of measurement
Answer assessment test using a special device to measure ABG

2

Description
BS(blood sugar)
Timepoint
Before Intralipid prescription and 6 hours after drug usage
Method of measurement
Assessment of blood biochemistry test answers using a special device to measure blood biochemistry

3

Description
BP(blood pressure)
Timepoint
Before Intralipid prescription and 30 minutes after drug usage
Method of measurement
by trained person by use of Sphygmomanometer

4

Description
EKG
Timepoint
Before Intralipid prescription and 30 minutes after drug usage
Method of measurement
by trained person by use of electerocadiogeraph device and reading ECG

5

Description
Blood NA
Timepoint
Before Intralipid prescription and 6 hours after drug usage
Method of measurement
Assessment of blood biochemistry test answers using a special device to measure blood biochemistry

6

Description
RR(respiratory rate)
Timepoint
Before Intralipid prescription and 30 minutes after drug usage
Method of measurement
By trained person by manually counting and simultaneously by monitoring devices to ensure

7

Description
PR(pulse rate)
Timepoint
Before Intralipid prescription and 30 minutes after drug usage
Method of measurement
By trained person by manually counting and simultaneously by monitoring devices to ensure

8

Description
T(temperature)
Timepoint
Before Intralipid prescription and 30 minutes after drug usage
Method of measurement
By trained person using medical mercury thermometer

9

Description
Blood K
Timepoint
Before Intralipid prescription and 6 hours after drug usage
Method of measurement
Assessment of blood biochemistry test answers using a special device to measure blood biochemistry

10

Description
Blood Urea
Timepoint
Before Intralipid prescription and 6 hours after drug usage
Method of measurement
Assessment of blood biochemistry test answers using a special device to measure blood biochemistry

11

Description
Blood Cr
Timepoint
Before Intralipid prescription and 6 hours after drug usage
Method of measurement
Assessment of blood biochemistry test answers using a special device to measure blood biochemistry

Intervention groups

1

Description
administration a bolus of 20cc/kg of 10% intralipid
Category
Treatment - Drugs

2

Description
Control group: no intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Yaft Abad Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Vice-Chancellor for research of Iran University of Medical Science and health services
Street address
Shahid Hemmat expressway-between Chamran and Sheykh Fazlollahe Nuri expresseay
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences and health services

Full name of responsible person
Bahareh Sepehrian, MD

Position
Forensic Medicine & Toxicology resident

Other areas of specialty/work

Street address
between Chamran and Sheykh Fazlollahe Nuri expresseay, Shahid Hemmat expressway

City
Tehran

Postal code

Phone
+98 912 719 6646

Fax

Email
b.sepehrian@stu.iums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences and health services

Full name of responsible person
Farrokh Taftachi, MD

Position
Forensic Medicine and Toxicology specialist

Other areas of specialty/work

Street address
Yaft Abad Hospital

City
Tehran

Postal code

Phone
+98 912 299 1963

Fax

Email
taftachi@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences and health services

Full name of responsible person
Hosein Sanaie Zadeh, MD

Position
Forensic Medicine and Toxicology spesialist

Other areas of specialty/work

Street address

City
Tehran

Postal code

Phone

Fax

Email

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