

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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.iuums.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  
expressey, 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 electrocardiograph 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

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**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**

## 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**

## 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*