

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Evaluation of the effect of hypertonic saline 3% in the treatment of ECG changes and other side effects of tramadol toxicity

#### Protocol summary

##### Study aim

Evaluation of the effect of hypertonic saline 3% in the treatment of ECG changes and other side effects of tramadol toxicity

##### Design

Randomized trial with not blinded in 200 patients, there is no control group, phase 2-3 on all of the patients

##### Settings and conduct

Evaluation of the effect of hypertonic saline 3% in tramadol side effects with ECG changes in emergency ward of Besat hospital in Tehran

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: acute tramadol poisoning; aged over 18 years. Exclusion criteria: severe disorders such as liver cirrhosis, the existence of previous diseases such as dextrocardia or behavioral disorders.

##### Intervention groups

Effect of hypertonic saline 3% in tramadol side effects in all of the patients, there is no control group

##### Main outcome variables

Drug dose, QRS widening, long QT, tall R, RBBB, axis deviation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220213054017N1**

Registration date: **2022-03-21, 1401/01/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-03-21, 1401/01/01**

Update count: **0**

##### Registration date

2022-03-21, 1401/01/01

##### Registrant information

##### Name

Ebrahim Karimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2235 3089

##### Email address

ebrahimkarimi86@ ajaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-23, 1400/07/01

##### Expected recruitment end date

2022-09-23, 1401/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of hypertonic saline 3% in the treatment of ECG changes and other side effects of tramadol toxicity

##### Public title

Effect of hypertonic saline 3% in tramadol toxicity

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Acute tramadol toxicity Aged over 18 years

###### Exclusion criteria:

Severe disorders such as liver cirrhosis Existence of previous diseases such as dextrocardia or behavioral disorders

##### Age

From **18 years** old  
**Gender**  
Both  
**Phase**  
2-3  
**Groups that have been masked**  
*No information*  
**Sample size**  
Target sample size: **200**  
**Randomization (investigator's opinion)**  
Not randomized  
**Randomization description**  
**Blinding (investigator's opinion)**  
Not blinded  
**Blinding description**  
**Placebo**  
Not used  
**Assignment**  
Single  
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

IR.AJAUMS.REC

**Street address**

No. 26,Abgari Ave,Kaj Squ,Saadat abad Blvd,Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1998656781

**Approval date**

2021-08-15, 1400/05/24

**Ethics committee reference number**

IR.AJAUMS.REC.1400.126

## Health conditions studied

### 1

**Description of health condition studied**

Acute tramadol toxicity and side effects

**ICD-10 code****ICD-10 code description**

## Primary outcomes

### 1

**Description**

QRS widening,QT prolongation,RBBB,Tall R,Axis deviation

**Timepoint**

Before and one hour after treatment with hypertonic saline3%

**Method of measurement**

ECG

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: For patients with ECG changes 3cc/kg saline 3% is given and one hour later the amount of ECG changes is checked

**Category**

Diagnosis

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Besat hospital and loghman hospital

**Full name of responsible person**

Ebrahim Karimi

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## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Dr.Mojtaba Yusefi

**Street address**

No.1,West Fatemi Ave.,Etemadzade Ave.,AJA University,tehran

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Ebrahimkarimi86@gmail.com

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Artesh 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**  
Artesh University of Medical Sciences

**Full name of responsible person**  
Ebrahim Karimi

**Position**  
Assistant professor

**Latest degree**  
Specialist

**Other areas of specialty/work**  
Medical Education

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## Person responsible for updating data

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**Position**  
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Yes - There is a plan to make this available

**Study Protocol**  
Yes - There is a plan to make this available

**Statistical Analysis Plan**  
Yes - There is a plan to make this available

**Informed Consent Form**  
Yes - There is a plan to make this available

**Clinical Study Report**  
Yes - There is a plan to make this available

**Analytic Code**  
Yes - There is a plan to make this available

**Data Dictionary**  
Yes - There is a plan to make this available

**Title and more details about the data/document**  
All data can be shared after people are not identified

**When the data will become available and for how long**  
Access started in 1402

**To whom data/document is available**

Researchers working in universities and hospitals

**Under which criteria data/document could be used**

For further research and change the therapeutic dose of the drug for greater effectiveness of the drug

**From where data/document is obtainable**

Correspond with the e- mail of the responsible author ,Ebrahimkarimi86@gmail.com,or call the mobile

number,00989124544838

**What processes are involved for a request to access data/document**

If a research proposal is submitted ,the data will be provided to the applicant within one month

**Comments**