

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1998656781

Phone

+98 21 2235 3089

Email

Ebrahimkarimi86@gmail.com

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

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email
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

Street address
West Fatemi., Etemadzade Ave., AJA university

City
Tehran

Province
Tehran

Postal code
1411718541

Phone
009886096350

Email
Ebrahimkarimi86@gmail.com

Person responsible for scientific 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

Street address

No.1, West Fatemi Ave., Etemadzade Ave., Aja university., Tehran

City
Tehran

Province
Tehran

Postal code
1411718541

Phone
+98 21 86430

Email
Ebrahimkarimi86@gmail.com

Person responsible for updating data

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

Street address
No.1, West Fatemi Ave., Etemadzade Ave., Aja university., Tehran

City
Tehran

Province
Tehran

Postal code
1411718541

Phone
+98 21 86430

Email
Ebrahimkarimi86@gmail.com

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