

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Investigation of the effect of Midazolam prophylaxis on the incidence of idiosyncratic seizures caused by tramadol consumption

Protocol summary

Study aim

Investigation of the effect of Midazolam prophylaxis on the incidence of idiosyncratic seizures caused by tramadol consumption

Design

The design of the study is a randomized clinical trial. The randomization method is blocked. Patients will be randomly divided into 2 groups based on 7 blocks. The sample size for each study group is 14.

Settings and conduct

In this study, all patients referred to Ali Asghar Hospital in Shiraz, due to tramadol use will be enrolled. Patients will be randomly divided into 2 groups based on 7 blocks. The sample size for each study group is 14. A total of 28 patients will be examined. Patients and data analyzer will be blind.

Participants/Inclusion and exclusion criteria

In this study, all patients referred to Ali Asghar Hospital in Shiraz, due to tramadol usage will be enrolled. Inclusion criteria: Age over 16 years, No seizures before entering the study. Exclusion criteria: Age over 70 years, History of epilepsy, Concomitant usage of antidepressants, Concomitant usage of other drugs with a dose of poisoning, History of underlying diseases, Trauma to the head.

Intervention groups

In intervention group, Midazolam will be given as an infusion at a dose of 0.05 mg / kg for 6 hours. In control group, Control group: Normal saline will be given an infusion for 6 hours.

Main outcome variables

Seizures, Number of seizures, Length of hospital stay, Need for mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180608040013N2**

Registration date: **2020-04-22, 1399/02/03**

Registration timing: **prospective**

Last update: **2020-04-22, 1399/02/03**

Update count: **0**

Registration date

2020-04-22, 1399/02/03

Registrant information

Name

Najmeh Zarei jelyani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3630 2747

Email address

n_zarei@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-09, 1399/02/20

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of Midazolam prophylaxis on the incidence of idiosyncratic seizures caused by tramadol consumption

Public title

effect of Midazolam prophylaxis on the seizures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Take tramadol tablets for the past 6 hours Age over 16 years No seizures before entering the study

Exclusion criteria:

Age over 70 years History of epilepsy Concomitant use of antidepressants Concomitant use of other drugs with a dose of poisoning History of underlying diseases Trauma to the head

Age

From **16 years** old to **70 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups. In order to randomize, a random block method will be used. For this purpose, we formed blocks with 8 person. In each block, 4 individuals will be in intervention group and 4 will be in control group. A total of 7 blocks will be considered for sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

Data will be analyzed by person who is blind to study groups. The therapist and patients will also be unaware of the type of treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Karim khan zand Ave, Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2019-04-07, 1398/01/18

Ethics committee reference number

IR.SUMS.MED.REC.1398.004

Health conditions studied

1

Description of health condition studied

Seizures

ICD-10 code

F44.5

ICD-10 code description

Conversion disorder with seizures or convulsions

Primary outcomes

1

Description

Seizures

Timepoint

Up to 24 hours after hospitalization

Method of measurement

Based on the patient's records and interview with the patient in case of discharge before 24 hours

2

Description

Number of seizures

Timepoint

Up to 24 hours after hospitalization

Method of measurement

Based on the patient's records and interview with the patient in case of discharge before 24 hours

3

Description

The length of hospital stay

Timepoint

From hospitalization to discharge

Method of measurement

Based on patient records

4

Description

Need for mechanical ventilation

Timepoint

From hospitalization to discharge

Method of measurement

Based on patient records

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Midazolam will be given an infusion at a dose of 0.05 mg / kg for 6 hours.

Category

Treatment - Drugs

2

Description

Control group: Normal saline will be given an infusion for 6 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar Medical and Educational Center

Full name of responsible person

Najmeh Zarei Jelyani

Street address

Meshkin Fam Street, Hazrat Ali Asghar Medical and Educational Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammadjavad Ashraf

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Najmeh Zarei Jelyani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available