

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of The Effect of Melatonin on Treatment of Pediatric Refractory and Super-Refractory Generalized Convulsive Status Epilepticus in 1 to 15 years old Children

Protocol summary

Study aim

Determining the effect of melatonin in the treatment of refractory and super-refractory generalized convulsive status epilepticus and the factors affecting it in children aged 1 to 15 years old.

Design

randomized controlled clinical trial (pilot study), parallel group, single blind, 40 participants.

Settings and conduct

This study will be conducted in the Shiraz Namazi Hospital PICU. According to the group they are placed in, the patients will or will not receive melatonin in addition to the standard treatment, and their condition will be evaluated by the pediatric ICU fellowship physician. The study is single blinded (Children and their legal guardian are not informed about the allocation of melatonin)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 1 to 15 years old admitted to Shiraz Namazi Hospital PICU with the diagnosis of refractory and super-refractory generalized convulsive status epilepticus Exclusion criteria: dissent of patient's legal guardian regarding administration of melatonin, inability to use NG tube for any reason, occurrence of adverse drug reaction to melatonin

Intervention groups

The intervention group consists of patients with refractory and super-refractory status epilepticus who will receive standard treatment including two lines of antiseizure drugs and then melatonin at the same time as anesthetic drugs. The comparison group consists of patients with refractory and super-refractory status epilepticus who will receive standard treatment including two lines of antiseizure drugs and then anesthetic drugs.

Main outcome variables

seizure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181014041338N2**

Registration date: **2023-01-22, 1401/11/02**

Registration timing: **prospective**

Last update: **2023-01-22, 1401/11/02**

Update count: **0**

Registration date

2023-01-22, 1401/11/02

Registrant information

Name

hamid nemati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3623 4508

Email address

meshham5@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-01, 1401/11/12

Expected recruitment end date

2023-08-01, 1402/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of The Effect of Melatonin on Treatment of Pediatric Refractory and Super-Refractory Generalized Convulsive Status Epilepticus in 1 to 15 years old Children

Public title

Effect of Melatonin in treatment of Pediatric Status Epilepticus

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1 to 15 years old children admitted in Namazi hospital PICU diagnosed with refractory and super-refractory generalized convulsive status epilepticus

Exclusion criteria:

Dissent of patient's legal guardian regarding administration of melatonin. Inability to use NG tube for any reason. Occurrence of adverse drug reaction to melatonin.

Age

From **1 year** old to **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize the allocation of melatonin to patients, block randomization method (two blocks of 20, one for receiving melatonin and one for not receiving melatonin) is used, the unit of which is individual. To achieve this goal, web-based randomization (www.randomization.com website) is used to randomly determine how 40 patients are placed in two groups of 20 (randomly placing numbers 1 to 40 in two groups of 20)

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, single blinding is used and only participants (patients and their legal guardians) have been kept blind. Since the patients are minors and the informed consent for participating in the study is obtained from their parents/guardians, the parent/guardian will also be blinded to receiving or not receiving melatonin. The other people involved in the study are all aware of the allocation or non-allocation of melatonin to patients. Since this is a pilot study and melatonin will be used after two antiseizure drugs and simultaneously with anesthetic drugs and in patients with decreased level of consciousness (through nasogastric tube), placebo will not be used in the control group.

Placebo

Not 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

Zand St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2022-06-14, 1401/03/24

Ethics committee reference number

IR.SUMS.MED.REC.1401.149

Health conditions studied**1****Description of health condition studied**

Pediatric status epilepticus

ICD-10 code

G40.411

ICD-10 code description

Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus

Primary outcomes**1****Description**

Cessation of generalized convulsive status epilepticus

Timepoint

Continuous 24-hour monitoring from the moment the patient enters the pediatric intensive care unit

Method of measurement

Clinical observation by PICU's attending physician and staff

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

2

Description

Control group:

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Meshkat Nemati

Street address

Namazi Sq, shiraz, fars.

City

shiraz

Province

Fars

Postal code

7193613311

Phone

+98 71 3647 4332

Email

nemazee_inf@sums.ac.ir

Web page address

<https://namazi.sums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahtab Memarpour

Street address

Namazi Hospital, Namazi sq, Shiraz, Fars,

City

shiraz

Province

Fars

Postal code

7193613311

Phone

+98 71 3647 4332

Email

nematih@sums.ac.ir

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

Hamid Nemati

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

Street address

Namazi sq, Shiraz, Fars,

City

Shiraz

Province

Fars

Postal code

7193613311

Phone

+98 71 3647 4332

Fax

Email

meshham5@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hamid Nemati

Position

Assistant professor

Latest degree

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Other areas of specialty/work

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Namazi sq, Shiraz, Fars,

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Fax
Email
meshham5@gmail.com

Fars
Postal code
7193613311
Phone
+98 71 3647 4332
Fax
Email
meshham5@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Nemati
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Neurology
Street address
Namazi sq, Shiraz, Fars,
City
Shiraz
Province

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available