

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the effectiveness of melatonin and clobazam in the prophylaxis of febrile seizures

#### Protocol summary

##### Study aim

Comparison of melatonin with clobazam as prophylactic agents from recurrent febrile seizures, a randomized clinical trial

##### Design

Clinical trial with a control group, with parallel groups, unblinded, non-randomized, phase 3 on 60 patients

##### Settings and conduct

In Bahrami Children's Hospital, Tehran, to investigate the effect of two drugs for the prophylaxis of febrile seizure

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The age of six months to 5 years and presenting with the second febrile seizure  
Exclusion criteria: History of receiving medication for prophylaxis, History of epilepsy or other neurological disorders

##### Intervention groups

Intervention group: Children aged 6 to 60 months with two simple febrile seizures who received melatonin during the first 48 hours of febrile illness. Control group: Children aged 6 to 60 months with two simple febrile seizures who received clobazam during the first 48 hours of febrile illness.

##### Main outcome variables

The recurrence of subsequent attacks of simple febrile seizures; Identification of drug side effects

#### General information

##### Reason for update

##### Acronym

FC

##### IRCT registration information

IRCT registration number: **IRCT20221102056380N1**

Registration date: **2023-08-26, 1402/06/04**

Registration timing: **retrospective**

Last update: **2023-08-26, 1402/06/04**

Update count: **0**

##### Registration date

2023-08-26, 1402/06/04

##### Registrant information

###### Name

Nahid Khosroshahi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7301 3000

###### Email address

n\_khosroshahi@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-01, 1399/07/10

##### Expected recruitment end date

2021-10-02, 1400/07/10

##### Actual recruitment start date

2020-10-01, 1399/07/10

##### Actual recruitment end date

2022-03-20, 1400/12/29

##### Trial completion date

2022-03-20, 1400/12/29

##### Scientific title

Comparing the effectiveness of melatonin and clobazam in the prophylaxis of febrile seizures

##### Public title

Comparing the effectiveness of melatonin and clobazam in the prophylaxis of febrile seizures

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Children aged Twelve months to 5 years It is the patient's second febrile seizure

**Exclusion criteria:**

History of receiving medication for prophylaxis History of epilepsy or other neurological disorders History of developmental delay

**Age**

From **12 months** old to **5 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Not 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**

Research Ethics Committee of Children's Medical Center, Tehran University of Medical Sciences

**Street address**

No. 62, Children's Medical Center, Dr. Gharib St., End of Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733151

**Approval date**

2020-12-26, 1399/10/06

**Ethics committee reference number**

IR.TUMS.CHMC.REC.1399.168

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

Febrile Seizure

**ICD-10 code**

R56.00

**ICD-10 code description**

Simple febrile convulsions

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

The recurrence of subsequent attacks of simple febrile seizures

**Timepoint**

6 and 12 months after the start of the intervention in children with febrile seizures

**Method of measurement**

Questions from parents

**2****Description**

Identification of drug side effects

**Timepoint**

6 and 12 months after the start of the intervention in children with febrile seizures

**Method of measurement**

Questions from parents

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: During the first 48 hours of febrile illness, melatonin at the dose of 0.3 mg/kg is given orally to children every 8 hours. The melatonin tablet contains 3 mg of the active substance, manufactured by Razak Iran.

**Category**

Prevention

**2****Description**

Control group: In the first 48 hours of febrile illness, clobazam is given orally to children every 12 hours. The dose of clobazam is adjusted based on the child's weight (less than 5 kg: one quarter of a tablet, 5 to 10 kg: one half of a tablet, 10 to 15 kg: three quarters of a tablet and more than 15 kg one tablet). Clobazam tablets contain 10 mg of active ingredient, manufactured by Hakim Iran.

**Category**

Prevention

**Recruitment centers****1****Recruitment center**

**Name of recruitment center**

Bahrami Children's Hospital

**Full name of responsible person**

Nahid Khosroshahi

**Street address**

Damavand St

**City**

Tehran

**Province**

Tehran

**Postal code**

1641744991

**Phone**

+98 21 7301 3000

**Fax**

+98 21 7756 9809

**Email**

n\_khosroshahi@tums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Akbar Fotouhi

**Street address**

Tehran University of Medical Sciences, corner of Qods St., Keshavarz Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Phone**

+98 21 81631

**Email**

tumspr@tums.ac.ir

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Nahid Khosroshahi

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Neurology

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Bahrami Children's Hospital, Damavand St

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**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**

Yes - There is 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

**Title and more details about the data/document**

There is no further information

**When the data will become available and for how long**

There is no further information

**To whom data/document is available**

There is no further information

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

There is no further information

**From where data/document is obtainable**

There is no further information

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

There is no further information

**Comments**