

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Efficacy of Rameleteon in pediatrics and adolescent patients aged more than 5 years with drug resistancegenetic epilepsy syndromes

Protocol summary

Study aim

In this study, which is to be designed as a clinical trial, the effect of a repurposed drug will be investigated on seizure frequency and quality of life in these patients.

Design

his study is a single arm open label quasi-experimental clinical trial (before and after) in which twenty patients will be compared regarding seizures frequency before and after treatment.

Settings and conduct

20 patients with treatment-resistant genetic epilepsy syndromes from the epilepsy centers of Tehran University of Medical Sciences, over 5 years of age, who meet the inclusion criteria, were selected and randomly divided into two groups to receive two doses of 8 and 1 mg. per day of Remiltion tablets divided into four meals per day for three months. This study is a semi-experimental (before and after) single arm open label clinical trial study and the patients are compared with the amount of seizures before the start of treatment in terms of seizure control.

Participants/Inclusion and exclusion criteria

Inclusion criteria is over 5 years patients with drug resistance genetic epilepsy syndromes and with a minimum seizure frequency of 20 seizures per month

Intervention groups

Ramelteon tablet (8mg/day and 1mg/day divided into four parts) will be used orally for tree months.

Main outcome variables

Seizure frequency reduction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110628006907N19**

Registration date: **2023-12-01, 1402/09/10**

Registration timing: **prospective**

Last update: **2023-12-01, 1402/09/10**

Update count: **0**

Registration date

2023-12-01, 1402/09/10

Registrant information

Name

Mahmoudreza Ashrafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6612 9252

Email address

ashrafim@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-05, 1402/10/15

Expected recruitment end date

2024-02-04, 1402/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Rameleteon in pediatrics and adolescent patients aged more than 5 years with drug resistancegenetic epilepsy syndromes

Public title

Efficacy of Rameleteon in pediatrics and adolescent patients aged more than 5 years with drug resistancegenetic epilepsy syndromes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Minimum seizure frequency should be 20 seizures per month Minimum age should be 5 years old

Exclusion criteria:

If the patient can not swallow the tablet.

Age

From 5 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

N/A

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

Ethics committee of Tehran University of Medical Sciences, medical faculty, ethics in research commi

Street address

Office of the Vice Chancellor for Research, First Floor, Building No. 1 of the Faculty of Medicine, Poursina St. North Door of the University, Ghods St, Enghelab St.

City

Tehran

Province

Tehran

Postal code

1111111111

Approval date

2023-09-05, 1402/06/14

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.322

Health conditions studied

1

Description of health condition studied

Drug resistance genetic epilepsy syndromes

ICD-10 code

G40.3

ICD-10 code description

Generalized idiopathic epilepsy and epileptic syndromes

Primary outcomes

1

Description

Seizure frequency

Timepoint

Measurement of seizure frequency one month before the study (before the intervention) and 1, 2 and 3 months after the start of Remeltion

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Decreased quality of life caused by treatment

Timepoint

Measuring the quality of life one month before the study (before the start of the intervention) and 1, 2 and 3 months after the start of Rameltion

Method of measurement

Questionnaire

2

Description

Emergence of new types of seizures in patients

Timepoint

Measuring the quality of life one month before the study (before the start of the intervention) and 1, 2 and 3 months after the start of Rameltion

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Twenty patients with drug resistance genetic epilepsy syndromes with Ramelteon treatment by the dose of 1 and 8 mg/day orally divided into four parts for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Epilepsy centers of Tehran University of Medical

Sciences

Full name of responsible person

Sareh Hosseinpour

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No. 62, Pediatric Medical Center, Dr. Gharib street

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Phone

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hosseinpour.sare@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Institute for Orphan Drug Discovery

Full name of responsible person

Elham Shojaeinia

Street address

Stresemannstrasse 46

City

Bremerhaven

Postal code

27570

Phone

+49 35262 1163034

Email

contact.iodd@protonmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Institute for Orphan Drug Discovery

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

DE

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sareh Hosseinpour

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Full name of responsible person

Mahmoodreza Ashrafi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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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

Pending

When the data will become available and for how long

Pending

To whom data/document is available

Pending

Under which criteria data/document could be used

Pending

From where data/document is obtainable

Pending

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

Pending

Comments

Pending