Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of Ramelteon in pharmacoresistant patients with Dravet syndrome aged more than 6 years in the pediatric epileptic centers in seizures control

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

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

Settings and conduct

Primary and secondary consequences will be evaluated in the TUMS epilepsy centers patients. The primary consequences are the seizures frequency and life quality, and any other treatments side effects will be considered as secondary consequences. In case of dissatisfaction of the participant and patient's guardian or the occurrence of life-threatening complications, the patient will be excluded from the study. All information is entered into SPSS software and the effectiveness of the drug on the desired initial outcome: reduction of seizure frequency to 30 percent compared to before receiving the drug and other consequences in patients are statistically analyzed. Frequent measurement of variables: To report quantitative variables, if the data is normal, the mean and standard deviation will be used, and if the normality is not established, the mean and amplitude will be used. If the normality hypothesis is established, the analysis of variance test for repeated measures (ANOVA) will be used, otherwise the Friedman test will be replaced. The McNemar test will also be used to examine the relationship between qualitative variables. Using spss software will run at 5% error level.

Participants/Inclusion and exclusion criteria

Inclusion criteria is over 6 years patients with Dravet syndrome and with a minimum seizure frequency of 6 seizures per month

Intervention groups

8mg/day Ramelteon tablet divided into two 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: **IRCT20220105053639N1**
Registration date: **2022-04-19, 1401/01/30**
Registration timing: **prospective**

Last update: **2022-04-19, 1401/01/30**
Update count: **0**

Registration date

2022-04-19, 1401/01/30

Registrant information

Name

Mahmoud Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6147 2751

Email address

mahmoh365@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2022-05-15, 1401/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Ramelteon in pharmacoresistant patients with Dravet syndrome aged more than 6 years in the pediatric epileptic centers in seizures control

Public title

Efficacy of Ramelteon in pharmacoresistant patients with Dravet syndrome aged more than 6 years in the pediatric epileptic centers in seizures control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Minimum seizure frequency should be 6 seizures per month Minimum age should be 6 years old

Exclusion criteria:

If the patient can not swallow the tablet.

Age

From **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

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

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

2021-12-29, 1400/10/08

Ethics committee reference number

IR.TUMS.CHMC.REC.1400.203

Health conditions studied

1

Description of health condition studied

Dravet Syndrome

ICD-10 code

G40.83

ICD-10 code description

Polymorphic epilepsy in infancy (PMEI)

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 treatment

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Any outcome other than reducing the frequency of seizures and improving the quality of treatment (side effect) is considered a secondary consequence.

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

Intervention groups

1

Description

Intervention group: Ten patients with Dravet syndrom with Ramelteon treatment by the dose of 8 mg/day orally divided into two 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

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

City
Tehran

Province
Tehran

Postal code
1419733151

Phone
+98 21 6693 0024

Fax
+98 21 6693 0024

Email
hosseinpour.sare@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Theracule AS

Full name of responsible person
Elham Shojaeinia

Street address
Oslo Science Park Gaustadalleen 21 0349 Oslo

City
Oslo

Postal code
0349

Phone
+47 948 36 983

Fax

Email
elham@theracule.com

Grant name

Grant code / Reference number

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

Title of funding source
Theracule AS

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
NO

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

Street address
Children's Medical Center, No. 62, next to Imam Khomeini Hospital, Dr. Mohammad Gharib St

City
Tehran

Province
Tehran

Postal code
1419733151

Phone
+98 21 6693 0024

Fax
+98 21 6693 0024

Email
hosseinpour.sare@gmail.com

Web page address
https://chmc.tums.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mahmoud Mohammdi

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Neurology

Street address
Children's Medical Center, No. 62, next to Imam Khomeini Hospital, Dr. Mohammad Gharib St

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mahmoh365@yahoo.com

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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