

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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 three 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 pharmaco-resistant patients with Dravet syndrome aged more than 6 years in the pediatric epileptic centers in seizures control

**Public title**  
Efficacy of Ramelteon in pharmaco-resistant 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 Remelction 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 Remelction

**Method of measurement**

Questionnaire

**Intervention groups**

1

**Description**

Intervention group: Ten patients with Dravet syndrome 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

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**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

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<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

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**Person responsible for updating data**

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**Email**

hosseinpour.sare@gmail.com

**Web page address**

**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