

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison between the effect of carbamazepine and levetiracetam usage in the treatment of children between 6 to 12 years old with Rolandic epilepsy; An open-labeled RCT

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Comparison between the effect of carbamazepine & levetiracetam usage in the treatment of children between 6 to 12 years old with Rolandic epilepsy

Design

Two arms parallel-group randomized trial opened labeled, on 88 participants using block randomization using rand function of excel software.

Settings and conduct

patients who were referred with the rolandic syndrome after conducting EEG and verification of the syndrome, participants go under WISC test and then using the randomization patients receive intervention and would be supervised monthly and after 3 months WISC test would be repeated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children between age 6-12 years old diagnosed with the rolandic syndrome having no previous history of neurological and/or psychiatric and/or learning and/or genetical disorder(s) previous to the onset of RS Exclusion criteria: having a previous history of using Anti-epileptic drugs

Intervention groups

The intervention group includes patients with rolandic epilepsy who receive levetiracetam drug intervention. The control group includes patients with rolandic epilepsy who receive carbamazepin drug intervention.

Main outcome variables

1. cognitive score 2. rate of epilepsy attacks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181014041338N1**

Registration date: **2022-01-16, 1400/10/26**

Last update: **2022-01-16, 1400/10/26**

Update count: **0**

Registration date

2022-01-16, 1400/10/26

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

2021-10-22, 1400/07/30

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the effect of carbamazepine and levetiracetam usage in the treatment of children between 6 to 12 years old with Rolandic epilepsy; An open-labeled RCT

Public title

Comparison between the effect of carbamazepine and levetiracetam on children diagnosed with Rolandic epilepsy		Name of ethics committee Ethics committee of shiraz University of Medical Sciences	
Purpose	Treatment	Street address	Zand St., Shiraz, Iran
Inclusion/Exclusion criteria	Inclusion criteria: children between age 6-12 years old (age of onset of disorder and eligible for the cognitive test) diagnosed with Rolandic syndrome by using vEEG or EEG by a pediatric neurologist or epileptologist having no previous history of using AEDs (Anti-epileptic drugs) having no previous history of neurological and/or psychiatric and/or learning and/or genetical disorder(s) previous to the onset of Rolandic syndrome having no history of using drugs that affect cognitive abilities significantly signing ethical consent with total awareness and voluntary		
	Exclusion criteria: patients who showed any side effects of Carbamazepine (like skin rash, Steven Johnson) and Levetiracetam (like suicide thoughts, acute behavioral problems due to Levetiracetam usage)		
Age	From 6 years old to 12 years old		
Gender	Both		
Phase	N/A		
Groups that have been masked	No information		
Sample size	Target sample size: 88		
Randomization (investigator's opinion)	Randomized		
Randomization description	Using Excel software and the Rand function in the software, the statistician of the project, will create a random sequence and hide this randomized allocation before the interventions begin. In this sequence, participants were randomly entered into 22 blocks, each consisting of two girls and two boys (each block consist of 4 individuals), in random order. Then 11 blocks would be given carbamazepine and another 11 blocks would receive levetiracetam.		
Blinding (investigator's opinion)	Not blinded		
Blinding description			
Placebo	Not used		
Assignment	Parallel		
Other design features			
Secondary Ids	empty		
Ethics committees			
<u>1</u>			
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 2021-08-07, 1400/05/16 Ethics committee reference number IR.SUMS.REC.1400.381		
	Health conditions studied		
	<u>1</u>		
	Description of health condition studied patient diagnosed with Rolandic syndrome ICD-10 code G40.0 ICD-10 code description Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset		
	Primary outcomes		
	<u>1</u>		
	Description rate of preventing epilepsy attacks Timepoint before the drug usage and 2 weeks, 1 and 3 months after the drug usage Method of measurement recording the number of epilepsy attacks viewed by family		
	<u>2</u>		
	Description cognitive test score Timepoint before the intervention and 3 months after it Method of measurement using WISC 5 TEST		
	Secondary outcomes		
	empty		
	Intervention groups		
	<u>1</u>		
	Description Control group: receiving Carbamazepine drug, Carbamazepine tab 200 mg (© Galinus Pharmaceuticals) within daily administration of 15-20 mg/kg maintenance		

dosage.
Category
Treatment - Drugs

2

Description

Intervention group: receiving Levetiracetam,
Levetiracetam tab 250 or 500 mg (© Cobel Darou) within
daily administration of 50 mg/kg maintenance dosage.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

Hamid Nemati

Street address

Namazi Sq, shiraz, fars.

City

shiraz

Province

Fars

Postal code

7134814734

Phone

+98 71 3212 7000

Email

emamreza@sums.ac.ir

Web page address

<https://emamreza.sums.ac.ir/page-EmamRezaClinic1/fa/91>

2

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Hamid 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

abbas rezaianzadeh

Street address

zand st, shiraz, fars.

City

shiraz

Province

Fars

Postal code

7134814336

Phone

+98 21 3230 5410

Email

info@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

Pediatrics

Street address

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City

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Postal code

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Email

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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

Subspecialist

Other areas of specialty/work

Pediatrics

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Email

meshham5@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

hossein bayat

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Speech therapy

Street address

rehab school of shiraz, abiverdi 1 st, chamran blvd,
shiraz, fars

City

shiraz

Province

Fars

Postal code

713451733

Phone

+98 71 3627 1552

Email

hossinebayatuniversity@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Demographic data and data related to final outcome will be shared by maintaining confidentiality.

When the data will become available and for how long

De-identified data will be available starting 1 year after publication.

To whom data/document is available

Academics employed at various research/university institutions and affiliated industries.

Under which criteria data/document could be used

For Academic and research goals only.

From where data/document is obtainable

Hamid Nemati, Imam Reza clinic, Namazi sq, shiraz
meshham5@gmail.com

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

The applicant would be asked to provide a formal request letter containing the importance of the data and the project processes. Following the receipt of the request letter, the data would be provided maxim within 1 month.

Comments