

Effect of levetiracetam monotherapy on the immune profile in children with epilepsy

Submission date 11/06/2026	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/06/2026	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/06/2026	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Epilepsy is a common neurological condition in children that causes repeated seizures. Levetiracetam is one of the most frequently prescribed medicines to control these seizures and is often used on its own (monotherapy). While it is known to be effective at stopping seizures, researchers want to understand if taking this medicine over a long period affects a child's immune system (the body's natural defense system). This study aims to evaluate whether 6 months of levetiracetam treatment causes any changes to the immunological profile (the balance of immune cells and proteins) in children with epilepsy.

Who can participate?

Children newly diagnosed with epilepsy who were scheduled to start treatment with levetiracetam monotherapy at the study center.

What does the study involve?

Participants had their immune profile assessed at two specific time points: first, at the very beginning before starting the medication, and second, after they had been taking levetiracetam consistently for 6 months. This involved collecting clinical data and blood samples to measure and compare immune markers at the start and end of the 6 months.

What are the possible benefits and risks of participating?

There was no direct clinical benefit to the participants. However, the results of this study will help doctors and scientists better understand how levetiracetam affects the developing immune system in children, which may help improve treatment safety. The risks were minimal and limited to the minor discomfort, brief pain, or bruising typically associated with providing a blood sample.

Where is the study run from?

The study was conducted at the Children's Medical Center, which is a tertiary children's referral center affiliated with the Tehran University of Medical Sciences (Iran).

When is the study starting and how long is it expected to run for?

January 2023 to September 2024.

Who is funding the study?
Tehran University of Medical Sciences (Iran).

Who is the main contact?
Golazin Shahbodagh Khan, Assistant Professor of Pediatric Neurology, Drshahbodagh@gmail.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Study information

Scientific Title

Impact of levetiracetam monotherapy on immunological profile in pediatric epilepsy: a prospective study

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

1. approved 11/04/2023, The Ethics Committee of Tehran University of Medical Sciences (Tehran University of Medical Sciences (Central Administration), Enqelab-e Eslami Ave., at the intersection with Qods St., Tehran, 1416753955, Iran; +98 21 6147 9999; vcr@tums.ac.ir), ref: IR. TUMS.MEDICINE.REC.1402.028

2. approved 05/06/2024, Research Ethics Committees of Children's Medical Center - Tehran University of Medical Sciences (Children's Medical Center Ethics Committee Dr Gharib Street, Keshavarz Boulevard, Tehran, 1419733151, Iran; -; chmc_research@tums.ac.ir), ref: IR.TUMS.CMHC.REC.1403.070

Primary study design

Interventional

Allocation

N/A: single arm study

Masking

Open (masking not used)

Control

Active

Assignment

Single

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Patients aged 2-18 years with a diagnosis of epilepsy, currently receiving Levetiracetam monotherapy.

Interventions

This study is designed as a prospective pre–post investigation in which each participant serves as their own control. Immunological indices—including IgG, IgA, IgM, IgG subclasses (IgG1–IgG4), anti-tetanus antibody titers, flow cytometry and WBCs will be assessed at two time points: prior to initiation of levetiracetam monotherapy and 6 months after treatment. To minimize confounding, children with acute infection at enrollment, known immune disorders, or current use of immunosuppressive medications will be excluded. All laboratory analyses will be performed at the Children's Medical Center laboratory.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Levetiracetam

Primary outcome(s)

1. Serum immunoglobulin G (IgG) concentration, as a marker of humoral immunity, measured using standard laboratory methods and validated assay kits to assess venous blood samples at

study entry (before initiation of levetiracetam monotherapy) and 6 months after initiation of levetiracetam monotherapy

2. Serum immunoglobulin G subclasses, including IgG1, IgG2, IgG3, and IgG4, as markers of humoral immunity, measured using standard laboratory methods and validated assay kits to assess venous blood samples, at study entry (before initiation of levetiracetam monotherapy) and 6 months after initiation of levetiracetam monotherapy

3. Serum immunoglobulin A (IgA) concentration, as a marker of humoral immunity, measured using standard laboratory methods and validated assay kits to assess venous blood samples, at study entry (before initiation of levetiracetam monotherapy) and 6 months after initiation of levetiracetam monotherapy

4. Serum immunoglobulin M (IgM) concentration, as a marker of humoral immunity, measured using standard laboratory methods and validated assay kits to assess venous blood samples, at study entry (before initiation of levetiracetam monotherapy) and 6 months after initiation of levetiracetam monotherapy

5. Serum anti-tetanus antibody titer, as an indicator of specific immune response measured using standard laboratory methods and validated assay kits to assess venous blood samples, at study entry (before initiation of levetiracetam monotherapy) and 6 months after initiation of levetiracetam monotherapy

6. T-cell subsets, including CD4+ and CD8+, measured using standard laboratory methods and validated assay kits to assess venous blood samples, at study entry (before initiation of levetiracetam monotherapy) and 6 months after initiation of levetiracetam monotherapy

Key secondary outcome(s)

1. Incidence of active infections (such as respiratory, gastrointestinal, or urinary tract infections) during the treatment period measured using data collected from parental reports, clinical examinations, and review of medical records, at the 6-month follow-up after initiation of levetiracetam monotherapy

Completion date

05/09/2024

Eligibility

Key inclusion criteria

1. Pediatric patients diagnosed with epilepsy
2. Age between 2 and 18 years
3. Patients who start levetiracetam as monotherapy
4. Informed consent obtained from parents or guardians

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

2 years

Upper age limit

18 years

Sex

All

Total final enrolment

30

Key exclusion criteria

1. Previous treatment with antiseizure drugs
2. Known immune disorders
3. Presence of acute infection during enrollment
4. Use of immunosuppressive medications

Date of first enrolment

15/04/2023

Date of final enrolment

01/04/2024

Locations

Countries of recruitment

Iran

Sponsor information

Organisation

Tehran University of Medical Sciences

ROR

<https://ror.org/01c4pz451>

Funder(s)

Funder type

Funder Name

Tehran University of Medical Sciences and Health Services

Alternative Name(s)

Tehran University of Medical Sciences, TUMS

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Iran

Results and Publications

Individual participant data (IPD) sharing plan

De-identified participant data including the primary and secondary study variables will be available after publication of the study results upon reasonable research request and with approval of the principal investigator, Dr Golazin Shahbodagh Khan, drshahbodagh@gmail.com.

IPD sharing plan summary

Available on request