

Suicidality in children and adolescents

Submission date 29/01/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/06/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/06/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In 2021, there was a 72% increase in suicides among 15-19-year-olds in Slovakia. This study aims to understand the relationship between suicidal thoughts and attempts and psychiatric diagnoses in children. It will also explore the impact of COVID-19 on these issues and identify potential predictors of suicidal behavior.

Who can participate?

Children and adolescents aged 10-17 years with suicidal thoughts or a history of suicide attempts in the last 7 days, who are registered at the Department of Paediatric Psychiatry of the Faculty of Medicine of the Comenius University and the National Institute of Children's Diseases in Bratislava. The control group will include 20 healthy volunteers not under psychiatric or psychological care.

What does the study involve?

Participants will fill out self-report questionnaires. An examiner will assess the severity of depressive symptoms and suicide risk using objective scales. Biological samples (blood, urine, hair) will be collected from both patients and healthy controls, processed using standard clinical methods, and stored at -80°C.

What are the possible benefits and risks of participating?

Participants may benefit from the detection of biomarkers not included in standard examinations. The only recorded risk is minor bruising from blood sample collection.

Where is the study run from?

The study will be conducted at the Department of Paediatric Psychiatry at Comenius University, Faculty of Medicine in Bratislava, and the National Institute of Children's Diseases in Bratislava, Slovakia.

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

April 2024 to December 2027.

Who is funding the study?

The study is funded by the Grant Agency of the Ministry of Education, Science, Research, and Sport of the Slovak Republic and the Slovak Academy of Science.

Who is the main contact?

Dr Jana Trebatická, jana.trebaticka@fmed.uniba.sk

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

VEGA 1/0183/24

Study information

Scientific Title

Suicidality in children and adolescents, neurobiological parameters, and their mutual association.

Acronym

NeuroSui

Study objectives

1. Determination of the prevalence of suicidal ideation and suicide attempts in children and adolescents hospitalized in pedopsychiatric inpatient wards concerning psychiatric diagnoses.
2. To determine neurobiological correlates with the focus on inflammatory markers (CRP, the neutrophil-to-lymphocyte ratio, fibrinogen, orosomucoid, neopterin), lipid profile (total cholesterol, LDL and HDL cholesterol, subfractions of HDL lipoproteins, cortisol, markers of oxidative and nitrosylation stresses (nitrotyrosine, lipoperoxides, 8-isoprostanes, AOPP, activity of glutathione peroxidase, catalase, SOD, glutamyl cysteinyl ligase (GCL), proteins of Nrf2/Keap1

/ARE signaling pathway and total plasma antioxidant capacity) in the child and adolescent patients with suicidal ideations and after suicide attempts compared to a control group of healthy children.

3. Determine the correlations between established neurobiological markers and psychopathological factors (incidence of suicidal ideation/suicide attempts, severity of depressive symptoms, presence of adverse life event) concerning age, gender, and diagnosis, and identify a potential predictive marker for use in clinical practice based on the results.

4. Investigate a potential relationship between overcoming a COVID-19 infection and the incidence of suicidal ideation and suicide attempts and neurobiological markers.

Ethics approval required

Ethics approval required

Ethics approval(s)

1. approved 23/04/2024, Ethics Committee of the National Institute of Children's Diseases and the Faculty of Medicine, Comenius University Bratislava (Limbová 1, Bratislava, 83340, Slovakia; +421 259371209; detska.klinika@nudch.eu), ref: EK4/1/2024

2. approved 17/09/2024, Ethics Committee of the National Institute of Children's Diseases and the Faculty of Medicine, Comenius University Bratislava (Limbová 1, Bratislava, 83340, Slovakia; +421 259371209; detska.klinika@nudch.eu), ref: EK9/2/2024

Study design

Single-center observational case-control study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Incidence of suicide attempts in the last seven days, Incidence of suicidal ideations.

Interventions

The research group will consist of 60 patients who will be divided into two groups: patients with suicidal ideations (SI) and patients after suicide attempts (SA).

The enrolled patients will be asked to fill out the following scales: the self-report Symptom Checklist 90 (SCL90R), the Child Depression Inventory (CDI) self-report questionnaire, and the self-report Yale Vermont Adversity in Childhood Scale (Y-VACS-SR)

The examiner will investigate depressive symptoms severity using the Children's Depression Rating Scale-Revised (CDRS-R) and suicide risk using the Columbia Suicide Severity Rating Scale (C-SSRS).

Biological material (blood, urine, hair) of patients and healthy controls will be collected, processed using standard clinical biochemistry methods, and stored at -80° C.

Intervention Type

Other

Primary outcome(s)

1. Prevalence of suicidal ideation is measured using the self-report Symptom Checklist 90 (SCL90R) at a single time point
2. Prevalence of suicide attempts is measured using the self-report Symptom Checklist 90 (SCL90R) at a single time point
3. Depressive symptoms severity is measured using the Children's Depression Rating Scale Revised (CDRSR) at a single time point
4. Suicide risk is measured using the Columbia Suicide Severity Rating Scale (CSSRS) at a single time point
5. Depressive symptoms in children and adolescents are measured using the Child Depression Inventory (CDI) self-report questionnaire at a single time point
6. Childhood adversity is measured using the self-report Yale Vermont Adversity in Childhood Scale (YVACSSR) at a single time point
7. Impact of COVID-19 on mental health is measured using the self-report COVID-19 Yorkshire Rehabilitation Scale (C19YRS) at a single time point
8. Mental health evaluation in healthy controls is measured using the Children's Depression Rating Scale Revised (CDRSR) at a single time point

Key secondary outcome(s)

1. Total cholesterol is measured using standard methods in a commercial clinical laboratory at a single time point
2. LDL cholesterol is measured using standard methods in a commercial clinical laboratory at a single time point
3. HDL cholesterol is measured using standard methods in a commercial clinical laboratory at a single time point
4. ApoA is measured using standard methods in a commercial clinical laboratory at a single time point
5. ApoE is measured using standard methods in a commercial clinical laboratory at a single time point
6. hsCRP is measured using standard methods in a commercial clinical laboratory at a single time point
7. IL6 is measured using standard methods in a commercial clinical laboratory at a single time point
8. IL2 is measured using standard methods in a commercial clinical laboratory at a single time point
9. Fibrinogen is measured using standard methods in a commercial clinical laboratory at a single time point
10. Orosomucoid is measured using standard methods in a commercial clinical laboratory at a single time point
11. Neutrophil count is measured using standard methods in a commercial clinical laboratory at a single time point
12. Lymphocyte count is measured using standard methods in a commercial clinical laboratory at a single time point
13. Neutrophil to lymphocyte ratio is measured using standard methods in a commercial clinical laboratory at a single time point
14. LDL subfractions are measured using the Lipoprint system at a single time point
15. HDL subfractions are measured using the Lipoprint system at a single time point
16. BDNF is measured using Elisa kit at a single time point
17. Nrf2 is measured using Elisa kit at a single time point
18. Lipoperoxides are measured using spectrophotometry at a single time point
19. AOPP is measured using spectrophotometry at a single time point

- 20. Catalase activity is measured using spectrophotometry at a single time point
- 21. SOD activity is measured using kits in erythrocyte hemolysate at a single time point
- 22. GPx activity is measured using kits in erythrocyte hemolysate at a single time point
- 23. Total antioxidant capacity of plasma is measured using spectrophotometry at a single time point
- 24. GCL is measured using western blot (WB) at a single time point
- 25. Protein expression of antioxidant enzymes is measured using western blot (WB) at a single time point
- 26. Cortisol in hair is measured using commercial kits at a single time point
- 27. 8 isoprostanes in urine are measured using commercial kits at a single time point
- 28. Creatinine in urine is measured using commercial kits at a single time point
- 29. Signaling pathway proteins are measured using western blot (WB) at a single time point
- 30. Gene expression is measured using RT PCR at a single time point
- 31. Protein concentration is measured using the Western Blot method at a single time point
- 32. mRNA level is measured using the qRT-PCR method at a single time point
- 33. Lipoprotein subfractions are measured using the Lipoprint method at a single time point

Completion date

31/12/2027

Eligibility

Key inclusion criteria

- 1. Patients hospitalized at the Department of Paediatric Psychiatry of the Comenius University, Medical Faculty and the National Institute of Children's Diseases, age 10-17 years.
- 2. Signed informed consent by the legal guardian.
- 3. Verbal consent of the patient to be included in the project.
- 4. Presence of suicidal ideation and/or suicide attempts.
- 5. Children and adolescents are willing to provide blood, urine, and hair samples.

Participant type(s)

Healthy volunteer, Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

10 years

Upper age limit

17 years

Sex

All

Key exclusion criteria

Chronic somatic inflammatory and oncological disease

Date of first enrolment

01/02/2025

Date of final enrolment

30/06/2027

Locations

Countries of recruitment

Slovakia

Study participating centre

The National Institute of Children's Diseases

Limbová 1

Bratislava

Slovakia

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Sponsor information

Organisation

Grant Agency of the Ministry of Education, science, research and sport of the Slovak Republik and the Slovak Academy of Science

Funder(s)

Funder type

University/education

Funder Name

Univerzita Komenského v Bratislave

Alternative Name(s)

Univerzita Komenského, Comenius University in Bratislava, Comenius University

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request after the project is completed from Jana Trebatická, jana.trebaticka@fmed.uniba.sk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Slovak		12/02/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			12/02/2025	No	No