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Suicidality in children and adolescents

Submission date
29/01/2025

Recruitment status
Recruiting

Registration date
16/06/2025

Overall study status
Ongoing

Last Edited
16/06/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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, LDLand HDLcholesterol, subfractions of HDL lipoproteins, cortisol, markers of oxidative and nitrosylation stresses (nitrotyrosine, lipoperoxides, 8isoprostanes, 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
83340

Sponsor information

Organisation
Grant Agency of the Ministry of Education, science, research and sport of the Slovak Republík 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

Slovakia

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
Protocol file			12/02/2025	No	No