

Informed Consent Form

Parent/Legal Guardian Permission and Adolescent Assent

Official Title	A Randomized, Double-Blinded Clinical Trial to Evaluate the Effectiveness of Naltrexone in Improving Nonsuicidal Self-Injurious Behavior
NCT Number	NCT
Document Date	18 May 2026
Organization Study ID	2024-0057
IRB Number / Notification Date	2405-162-1540 / 30 March 2026
Sponsor	Seoul National University Hospital
Responsible Party	Yong-Min Ahn, MD, PhD, Department of Psychiatry, Seoul National University Hospital
Planned Study Start	June 2026
Planned Study Completion	December 2027
Planned Analysis Completion	within 6 months after study completion (target: June 2028)
Document Version	Version 2.0 - ClinicalTrials.gov public upload draft

This document contains no names of research participants.

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Study Title: A Randomized, Double-Blinded Clinical Trial to Evaluate the Effectiveness of Naltrexone in Improving Nonsuicidal Self-Injurious Behavior

ClinicalTrials.gov Identifier: NCT _____

Sponsor: Seoul National University Hospital

Principal Investigator: Yong-Min Ahn, MD, PhD, Department of Psychiatry, Seoul National University Hospital

IRB Number / Notification Date: 2405-162-1540 / 30 March 2026

1. Information for Parent/Legal Guardian

Your child is being asked to take part in a clinical research study evaluating naltrexone for nonsuicidal self-injury. Please read this form carefully and ask the study doctor or study staff any questions before deciding whether to allow your child to participate.

Participation is voluntary. You and your child may decide not to participate or may stop participation at any time without disadvantage or effects on usual medical care.

2. Information for the Adolescent Participant

You are being asked to join a research study because you have nonsuicidal self-injury. This study will test whether a medicine called naltrexone can help reduce self-injury. Some participants will receive naltrexone and some will receive placebo. Placebo looks like the study medicine but does not contain active medicine.

If you are 18 years old or younger, you may participate in this study, but you and your parent/legal guardian should know that the safety of the study medicine has not been established in people 18 years old or younger.

3. Purpose and Background

The purpose of this study is to evaluate whether naltrexone improves nonsuicidal self-injurious behavior. The effectiveness of naltrexone for nonsuicidal self-injury has not yet been established. Naltrexone is compared with placebo because a comparison is needed to test whether it may be helpful for nonsuicidal self-injury.

4. Study Product, Number of Participants, and Duration

- Investigational product: Whanin Naltrexone Tab. 50 mg; active ingredient naltrexone hydrochloride 50 mg; manufacturer Whanin Pharm. Co., Ltd.
- Total planned enrollment: 150 participants, with 75 participants per group.
- Treatment duration: 6 weeks after randomization.
- Planned study start: June 2026; planned study completion: December 2027; planned final analysis within 6 months after study completion.

5. Study Procedures

If the adolescent participant and parent/legal guardian agree and the participant is eligible, the participant will be randomly assigned to receive either naltrexone or placebo once daily for 6 weeks, both in addition to usual psychiatric treatment. The participant, parent/legal guardian, and outcome assessors will not know the assigned group during the study unless unblinding is needed for safety.

- Study visits include screening, baseline, week 2, week 4, and week 6, with an allowable visit window of +/-3 days after baseline.
- Study procedures include clinical interviews, questionnaires about self-injury, mood, anxiety, eating-related symptoms, and safety, medication diary review, and return of unused medication.
- Safety procedures include adverse event assessment, C-SSRS suicide risk assessment, physical examination, weight, BMI, vital signs, blood tests, urine tests, and electrocardiography according to the study schedule.
- A study smartphone application will be installed to collect weekly affect and urge/craving-related ratings and daily mood, exercise, and sleep ratings. Event-based entries may be completed when self-injurious urges or self-injury occur.

6. Risks, Benefits, and Alternatives

Possible risks include side effects of naltrexone, discomfort from blood or urine testing or electrocardiography, and emotional discomfort when discussing self-injury or suicidal thoughts. Expected naltrexone-related side effects include nausea, headache, dizziness, fatigue, nervousness, insomnia, anxiety, depressed mood, vomiting, and other symptoms. The study team will monitor safety throughout the study.

Participation may or may not directly benefit the adolescent participant. Information from this study may help improve future treatment options for people with similar symptoms. The alternative is not to participate and to receive usual clinical care, including medications or non-pharmacological treatments judged appropriate by the treating clinician.

7. Pregnancy, Breastfeeding, and Contraception

Participants who are pregnant or breastfeeding cannot participate. Pregnancy testing will be performed when applicable. Participants of childbearing potential must agree to use appropriate contraception during the required period. Male participants who have sexual intercourse with a partner of childbearing potential must agree to use appropriate barrier contraception during the required period.

8. Instructions and Prohibited Medications

The participant should attend scheduled visits, complete evaluations, take the study medication once daily as instructed, complete the medication diary, and return unused study medication and containers. The study doctor or study staff should be informed promptly about other medications, other medical visits, unwanted effects, injury, pregnancy, or possible pregnancy.

The following medications are prohibited during the study: disulfiram, thioridazine, and opioid analgesics.

9. Costs and Compensation

There will be no additional cost for study participation. All clinical evaluations for efficacy and safety assessment will be provided without cost to the participant.

Transportation reimbursement of KRW 50,000 will be provided after completion of each visit evaluation. Payment is expected within 1 month after completion of the required administrative process and may be adjusted according to the extent or duration of participation.

10. Confidentiality

Research data will be managed using coded identifiers whenever possible and kept confidential according to applicable privacy laws. Authorized monitors, auditors, the institutional review board, and regulatory authorities may review study-related records within the scope permitted by law. Results may be published or posted in public trial registries only after removal of personal identifiers and anonymization as required. Study-related records will be stored securely for 3 years after study completion and then appropriately destroyed.

11. Voluntary Participation and Withdrawal

Participation is voluntary. The parent/legal guardian may decide not to allow participation, and the adolescent participant may decide not to participate or may stop participation at any time. This decision will not affect usual medical care. The investigator may stop participation for safety reasons, serious adverse events, worsening medical status, clinically significant suicide risk, failure to follow study procedures, or other reasons judged appropriate by the investigator.

12. Contact Information

- Principal Investigator, Yong-Min Ahn: +82-2-2072-2457.
- Clinical trial research nurse: +82-2-2072-4053 / +82-10-8783-2451.
- Seoul National University Hospital Institutional Review Board: +82-2-2072-0694.
- Seoul National University Hospital Clinical Research Ethics Center: +82-2-2072-0368.

13. Parent/Legal Guardian Permission Statement

I have read and understood the information in this form. I have had the opportunity to ask questions, and my questions have been answered. I voluntarily give permission for the adolescent participant to participate in this study.

14. Adolescent Assent Statement

The study has been explained to me. I have had the chance to ask questions. I understand that I do not have to join the study and that I can stop at any time. I agree to participate in this study.

Adolescent Participant Name	
Adolescent Participant Assent Signature	Date (YYYY/MM/DD):
Parent/Legal Guardian Name	
Parent/Legal Guardian Signature	Date (YYYY/MM/DD):
Relationship to Participant / Reason for Representative Consent	
Investigator/Person Obtaining Consent Signature	Date (YYYY/MM/DD):