Informed Consent Form

Adult Participants

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.

Informed Consent Form

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. Invitation to Participate

You are being asked to consider participating in a clinical research study. This consent form provides information about the study. Please read it carefully, discuss it with the study doctor or study staff, and ask any questions at any time before deciding whether to participate.

Participation is voluntary. You may decide whether to participate or not, and you may stop participating at any time without penalty or disadvantage. Your decision will not affect the treatment of nonsuicidal self-injury or your usual medical care.

2. Purpose and Background of the Study

The purpose of this study is to evaluate whether naltrexone improves nonsuicidal self-injurious behavior. This study is conducted for research purposes, not as part of ordinary treatment, and the effectiveness of naltrexone for nonsuicidal self-injury has not yet been established.

Nonsuicidal self-injury has become a clinically important phenomenon. It may occur in several psychiatric conditions, including mood and anxiety disorders. Some patients with nonsuicidal self-injury show biological and psychological similarities to behavioral addictions. Naltrexone is a medication used for substance-related or behavioral addiction conditions. This study compares naltrexone with placebo to evaluate whether naltrexone may improve nonsuicidal self-injurious behavior.

3. Investigational Product

- Product name: Whanin Naltrexone Tab. 50 mg.
- Active ingredient: naltrexone hydrochloride 50 mg.
- Manufacturer: Whanin Pharm. Co., Ltd.
- Comparator: placebo that cannot be distinguished from the investigational product.

4. Number of Participants and Duration

This study will enroll a total of 150 participants diagnosed with nonsuicidal self-injury, with 75 participants in each group. Participants will be randomly assigned to receive either naltrexone 50 mg in addition to usual psychiatric treatment or placebo in addition to usual psychiatric treatment. Efficacy and safety will be evaluated over a total treatment period of 6 weeks.

The planned study start date is June 2026, the planned study completion date is December 2027, and final statistical analysis is planned within 6 months after study completion.

5. Study Procedures

If you voluntarily agree to participate and are judged eligible by the study doctor, you will sign this consent form before study-specific procedures are performed. Before registration, the study doctor will conduct examinations, interviews, clinical evaluations, and questions about medications.

After enrollment and baseline evaluation, you will be randomly assigned to one of two groups in a 1:1 ratio. You will visit the study site a total of five times, including screening, baseline, week 2, week 4, and week 6. Visits after baseline may be scheduled within +/-3 days of the planned visit date.

- Study procedures include eligibility review, demographic information, medical and psychiatric history, medication and non-pharmacological treatment review, and assessment of self-injurious behavior.

- Questionnaires and clinician-rated assessments may include Clinician-rated Severity of Nonsuicidal Self-Injury, ISAS, CTQ, DSHI, modified OCDS, MADRS, HAM-A, PHQ-9, GAD-7, EDE-Q, CGI-S, CGI-I, and C-SSRS.
- Safety assessments include physical examination, weight, BMI, vital signs, adverse event assessment, blood tests, urine tests, and electrocardiography according to the study schedule.
- You will be asked to take the investigational product once daily, preferably at a similar time each day, complete a medication diary, and return all unused medication and containers at each applicable visit.

6. Smartphone App-Based Assessments

If enrolled, you will install a study application on your personal smartphone. Through this app, you will complete self-report assessments. With your consent, the following data may be collected:

- Weekly PANAS affect ratings and modified OCS ratings, and daily time-based ecological momentary assessments of mood, exercise, and sleep.
- Event-based assessments when self-injurious urges occur, including PANAS ratings; and when self-injurious behavior occurs, including PANAS ratings, questions about suicidal intent, and selected self-injury-related statements.

Study staff may contact you by SMS, telephone, or other communication methods to remind you of interview schedules or encourage completion of study records.

7. Randomization and Blinding

Randomization means assignment by chance. You will have an equal chance of receiving naltrexone or placebo. This study is double-blinded, which means that you and the investigator evaluating you will not know which group you are assigned to during the study. Treatment assignments will be known after the study is completed and final analysis is performed.

If a serious adverse event or other urgent safety issue occurs, such as suicidal behavior or a serious side effect, study participation may be stopped and the treatment assignment may be disclosed if necessary for safety.

8. Instructions During Participation

Please follow the instructions of the study doctor and study staff. It is important that you attend scheduled visits, complete study evaluations, and take the investigational product according to the prescribed instructions. If you need to change a visit date, please discuss this with the study doctor.

If you take other medications, receive other diagnoses or treatments, visit another department or hospital, experience an unwanted effect, suspect an injury or side effect, or become pregnant or suspect pregnancy, please inform the study doctor or delegated study staff as soon as possible.

The following medications are prohibited during the study: disulfiram, thioridazine, and opioid analgesics. Other medications may be used if clinically appropriate and will be recorded.

9. Pregnancy, Breastfeeding, and Contraception

If you are pregnant or breastfeeding, you cannot participate in this study. A urine pregnancy test will be performed during screening when applicable. Participants of childbearing potential must agree to use appropriate and effective contraception from the time of consent until the end of study participation. Examples include prescription oral contraceptives, contraceptive injections or implants, contraceptive patches, intrauterine devices, partner sterilization, or abstinence.

Male participants who have sexual intercourse with a partner of childbearing potential must agree that they and their partner will use appropriate and effective barrier contraception, such as a condom with spermicide, from the time of consent until the end of study participation.

10. Alternatives to Participation

You do not have to participate in this study. If you do not participate, you may receive other treatments according to your preference and the judgment of your study doctor or treating physician. Medications sometimes used for mood or impulsivity symptoms include antidepressants, mood stabilizers, or anxiolytics. Non-pharmacological treatments such as cognitive behavioral therapy or dialectical behavior therapy may also be considered. These treatments may or may not improve nonsuicidal self-injury.

11. Possible Risks and Discomforts

This study reflects usual psychiatric treatment settings and uses a medication that has been used for substance-related and behavioral addiction conditions. Expected side effects of naltrexone include nausea, headache, and dizziness. These side effects are usually mild or moderate and temporary, but serious adverse events may occur.

- Central nervous system: headache, nervousness, insomnia, anxiety, depressed mood, suicidal thoughts, suicidal attempt, fatigue.
- Sensory system: dizziness, somnolence.
- Gastrointestinal system: nausea and vomiting.
- Other discomforts may include discomfort from blood sampling, urine testing, electrocardiography, and emotional discomfort when discussing self-injury or suicidal thoughts.

The study team will carefully monitor actual suicide risk at each visit using interviews and the C-SSRS. If the investigator judges that actual suicide risk is clinically high, the investigational product may be stopped and study participation may be discontinued.

12. Possible Benefits

This study is designed to evaluate the effect of the investigational product. It is not known whether your health status, including the frequency or severity of self-injury, will improve by participating. Information obtained from this study may help determine better treatment approaches for people with similar symptoms in the future.

13. Costs and Compensation

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

Transportation reimbursement of KRW 50,000 will be provided after completion of each visit evaluation. Reimbursement paperwork will be submitted after the evaluation is completed, and payment is expected within 1 month after completion of the required administrative process. The amount may be adjusted according to the extent or duration of study participation.

14. Voluntary Participation and Withdrawal

Participation is voluntary. You may refuse to participate or withdraw at any time without disadvantage, and you may continue to receive standard treatment after withdrawal. The study doctor may also stop your participation if you do not follow study procedures, if participation appears medically harmful, if a serious adverse event occurs, if your medical condition worsens, if clinically significant suicide risk is present, or if the investigator determines that continuing participation would interfere with the study or be unsafe.

15. New Information

If new scientific information or safety information becomes available during the study that may affect your decision to continue participating, the study team will inform you or your representative promptly so that you can decide whether to continue participation.

16. Injury and Compensation

The study team will make every effort to protect your safety. If physical injury or disease occurs as a result of the investigational product administered according to the protocol or medical treatment or procedures performed according to the protocol, compensation will be provided according to the clinical trial participant compensation policy, and appropriate medical treatment will be provided. Injuries resulting from failure to follow the protocol agreed with the investigator or from negligence may not be compensated.

17. Confidentiality

Records that can identify you will be managed confidentially using appropriate methods, including coded numbers, in accordance with applicable privacy laws. If study results are reported, published, or presented, your identity will remain confidential. Authorized monitors, auditors, the institutional review board, and regulatory authorities may review study-

related records, including medical records, within the scope permitted by law to verify the conduct of the study and quality of data. By signing this form, you permit such review while your confidentiality is protected.

Study-related data will be kept in a locked storage area for 3 years after study completion and then appropriately destroyed. Study results and clinical information may be registered in a public database in anonymized form after removal of personally identifiable information.

18. Contact Information

For problems, concerns, injuries, or other questions related to the clinical trial, you may contact the study doctor or study staff.

- 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.

19. Consent Statement

1. I have received an oral explanation of the clinical trial, read the information above, and discussed this study sufficiently with the study staff.
2. I have been informed of the risks and benefits of the study and have received satisfactory answers to my questions.
3. I voluntarily agree to participate in this study.
4. I understand that I may refuse participation or withdraw at any time without affecting my subsequent treatment and without disadvantage.
5. If applicable, I understand that I cannot participate if pregnant or breastfeeding, that pregnancy testing may be required, that I must inform the investigator immediately if pregnancy or possible pregnancy occurs, and that appropriate contraception must be used during the required period.
6. By signing this form, I agree that my personal information may be collected and processed by the investigator for medical research purposes within the scope permitted by applicable laws and regulations.
7. I understand that I will receive a copy of this information sheet and consent form.

Participant Name	
Participant Signature	Date (YYYY/MM/DD):
Investigator/Person Obtaining Consent Name	
Investigator/Person Obtaining Consent Signature	Date (YYYY/MM/DD):