ISRCTN12245577 https://doi.org/10.1186/ISRCTN12245577

Niacin skin flushing response in evaluating the efficacy of modified electroconvulsive therapy in schizophrenia

Submission date
09/02/2025

Recruitment status
No longer recruiting

Registration date
18/02/2025

Overall study status
Completed

Last Edited
10/03/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Schizophrenia is a group of chronic neurodevelopmental disorders. Drug therapy is the main treatment. Modified electroconvulsive therapy (MECT) is also considered an effective treatment method. The aim of this study was to explore the clinical characteristics of patients undergoing MECT treatment, including positive, negative, and general psychotic symptoms, and the improvement of these characteristics after treatment.

Who can participate?
Patients with schizophrenia aged 18-65 years who are registered at the Fourth People's Hospital of Wuhu

What does the study involve?
In this non-randomized study, a total of 70 hospitalized patients with schizophrenia underwent eligibility assessment. Participants were divided into two groups based on whether they met the criteria for treatment-resistant schizophrenia (TRS). Among the 40 patients with TRS, eight declined to undergo MECT. The remaining consenting patients received a 6-week course of MECT combined with antipsychotic medication (SZ-MECT group). Among the 30 patients with non-treatment-resistant schizophrenia (N-TRS), all patients agreed to participate in the study and underwent 6 weeks of antipsychotic medication treatment (SZ-N group).

What are the possible benefits and risks of participating?
Participants who receive the free treatment may benefit from a reduction in their depressive symptoms. There are no known risks involved with participating.

Where is the study run from?
The Fourth People's Hospital of Wuhu (China)

When is the study starting and how long is it expected to run for?
December 2022 to December 2025

Who is funding the study?
1. Health Commission of Anhui Province (China)
2. Department of Science and Technology of Anhui Province (China)

Who is the main contact?
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Study information

Scientific Title
Changes in psychiatric symptoms and niacin skin flushing response after modified electroconvulsive therapy, and the correlation between them in schizophrenia

Acronym
NSFR SZ

Study objectives

Current interventions as of 10/03/2025:
The primary aim of this study was to compare the clinical characteristics of patients with treatment-resistant schizophrenia (TRS) and non-treatment-resistant schizophrenia (N-TRS), including the severity of clinical symptoms and the niacin skin flushing response (NSFR), which is considered an auxiliary diagnostic biomarker for schizophrenia (SZ), and investigate the relationship between NSFR and the severity of symptoms. Additionally, this study also investigated whether the patients with TRS could achieve comparable clinical remission through modified electroconvulsive therapy (MECT) to that of the patients with N-TRS receiving conventional antipsychotic drugs, to provide further evidence in support of the efficacy of MECT in the treatment of SZ.

Previous interventions:
The aim of this study is to evaluate the relationship between the efficacy of modified electroconvulsive therapy and niacin skin flushing response in schizophrenia, and explore whether niacin skin flushing response is related to psychiatric symptoms.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/12/2023, Ethical Committee of the Fourth People's Hospital of Wuhu (The Fourth People's Hospital of Wuhu, Wuhu, 241000, China; -; whsyllwyh@163.com), ref: [2023]-KY-052

Primary study design
Interventional

Study design
Single-centre interventional non-randomized controlled trial

Study type(s)
Diagnostic, Treatment, Efficacy

Health condition(s) or problem(s) studied
Schizophrenia

Interventions
Current interventions as of 10/03/2025:
Participants were divided into two groups based on whether they met the criteria for treatment-resistant schizophrenia (TRS). Among the 40 patients with TRS, 8 declined to undergo MECT. The remaining consenting patients received a 6-week course of MECT combined with antipsychotic medication (SZ-MECT group, n = 32). Among the 30 patients with non-treatment-resistant schizophrenia (N-TRS), all patients agreed to participate in the study and underwent 6 weeks of antipsychotic medication treatment (SZ-N group, n = 30). The drugs include chlorpromazine, aripiprazole, olanzapine, and risperidone (appropriate dosage and frequency of medication based on the patient's condition). The MECT frequency is 2-3 times a week, adjusted according to the patient's condition.

Previous interventions:
The study recruited a total of 62 patients with schizophrenia. 30 schizophrenia individuals took only anti-psychotics (SZ-N group) and 32 schizophrenia patients received MECT combined with anti-psychotics (SZ-MECT group).

The research group combined MECT with antipsychotic drug treatment. The drugs include chlorpromazine, aripiprazole, olanzapine, and risperidone (appropriate dosage and frequency of medication based on the patient's condition). The MECT frequency is 2-3 times a week, adjusted according to the patient's condition. The follow-up time was at baseline, week 2, week 4, and week 6. The total treatment time is adjusted according to the patient's symptoms.

The control group was only treated with antipsychotic drugs, including clozapine, aripiprazole, olanzapine, and risperidone (appropriate dosage and frequency of medication based on the patient's condition).

All patients underwent Positive and Negative Syndrome Scale (PANSS) and niacin skin flushing response (NSFR) scores at baseline (t1) and follow-up (t2, ~4 weeks) time points. Group differences in changes of the NSFR between two schizophrenia groups over time, as well as the correlation between psychiatric symptoms and niacin skin flushing response, were assessed.

Intervention Type
Mixed

Primary outcome(s)
Psychiatric symptoms measured using the Positive and Negative Syndrome Scale (PANSS) at baseline, weeks 2, 4, and 6.

Key secondary outcome(s)
Niacin skin flushing response test using 6 different concentrations (triple gradient dilution from 60 mM) of niacin dropped onto the skin at baseline, week 2, 4, and 6

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Patients diagnosed according to the ICD10 (International Classification of Diseases, 10th Revision) criteria for SZ
2. 18 to 65 years old
3. PANSS score was within the range of 70~120

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit

65 Years

Sex
All

Total final enrolment
62

Key exclusion criteria
1. Severe neurological diseases or traumatic brain injury or substance dependence
2. Administration of non-steroidal or steroidal anti-inflammatory drugs within 2 weeks
3. MECT administration 1 month before admission
4. MECT contraindications (including anesthesia allergy, intracranial space-occupying lesions, active pulmonary inflammation, recent myocardial infarction, recent cerebral hemorrhage, retinal detachment, untreated glaucoma, etc)
5. Pregnancy

Date of first enrolment
01/01/2024

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
China

Study participating centre
The Fourth People's Hospital of Wuhu
Wuxiashan East Road
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Sponsor information

Organisation
The Fourth People's Hospital of Wuhu

Funder(s)

Funder type

Government

Funder Name
Health Commission of Anhui Province

Funder Name
Anhui Provincial Department of Science and Technology

Alternative Name(s)
Anhui Department of Science and Technology, , Department of Science and Technology of Anhui Province

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

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 from Bingbing Sui (19956720391@163.com)

IPD sharing plan summary
Available on request