

A study on the therapeutic effect of modified electroconvulsive therapy in refractory schizophrenia

Submission date 27/02/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/03/2024	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/03/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Treatment-resistant schizophrenia (TRS) tends to be protracted and difficult to cure. Commonly used prescription drugs include clozapine and risperidone, which can effectively alleviate the positive symptoms of patients. Long-term medication will inevitably affect the immune function of patients and may bring some side effects. Modified electroconvulsive therapy (MECT), which applies a short, moderate current to the brain, induces a brief state of unconsciousness and improves mental state. There is limited research on the combination of MECT with risperidone and psychotherapy in TRS. Therefore, this study aims to explore the effectiveness of MECT combined with risperidone and psychotherapy in improving the mood and symptoms of patients with TRS.

Who can participate?

Patients aged over 18 years old who have had TRS for over 5 years and have had previous treatment with two or more antipsychotic drugs of different chemical structures, each at a sufficient dosage, with no significant improvement after continuous treatment for more than 2 months

What does the study involve?

Participants were randomly divided into a control group and a study group, with the control group receiving risperidone tablets and psychotherapy, and the study group undergoing MECT as well as the control group treatment. The treatment lasted for 2 months.

What are the possible benefits and risks of participating?

Participants may get better results from the new treatments. Participants' immune function may also be affected by long-term medications, which are routine therapeutic drugs for TRS.

Where is the study run from?

Wuhan Wudong Hospital (China)

When is the study starting and how long is it expected to run for?
July 2017 to March 2020

Who is funding the study?
Wuhan Municipal Health Commission (China)

Who is the main contact?
Qiu-Ming Ji, jiqiuming79@163.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Efficacy of modified electroconvulsive therapy in treatment-resistant schizophrenia

Study objectives

To explore the efficacy of combining modified electroconvulsive therapy (MECT) with risperidone and psychotherapy in improving the emotions and symptoms of patients with treatment-resistant schizophrenia (TRS).

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 30/12/2017, Wuhan Wudong Hospital (No. 46 of Wudong Street, Qingshan District, Wuhan , 430084, China; +86 (0)27 50528367; 281970698@qq.com), ref: WDYY-LL-2017-12

Study design

Randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Treatment-resistant schizophrenia

Interventions

Participants were randomly divided into a control group and a study group, with the control group receiving risperidone tablets and psychotherapy, and the study group undergoing MECT as well as the control group treatment.

The control group took risperidone tablets orally. The daily dose was 1 mg at the beginning of medication, and the medication was continued for 7 days. Subsequently, the dose is gradually increased to 4~6 mg per day. According to the patient's individual situation, the drug dosage was adjusted as needed to ensure that the maximum daily dose was less than 6 mg. Psychotherapists assessed the patients' mental status every week during their hospitalization and actively provided positive psychotherapy and guidance. The treatment lasted for 2 months.

The study group received MECT treatment on the basis of the control group. MECT treatment is performed three times a week, and the frequency is gradually reduced according to the specific conditions of patients. A course of treatment includes about 8~12 courses, which last for about 2 months.

Risperidone tablets (Xi'an Janssen Pharmaceutical Ltd., Xi'an, China; Chinese Pharmacopoeia Registration Number H20010309)

The Thymatron® System IV (America)

1 mg of atropine (Wuhu Kangqi Pharmaceutical Co., Ltd., Wuhu China; Chinese Pharmacopoeia Registration Number H34021900)

1.5 mg/kg propofol (Guangdong Jiabo Pharmaceutical Co., Ltd., Guangdong China; Chinese Pharmacopoeia Registration Number H20051843)

1–1.5 mg/kg of succinylcholine chloride (Shanghai Xudong Haipu Pharmaceutical Co., Ltd., Shanghai China; Chinese Pharmacopoeia Registration Number H31020599)

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Risperidone, Thymatron® System IV, atropine, propofol, succinylcholine chloride

Primary outcome(s)

Severity of positive and negative symptoms assessed using the Positive and Negative Syndrome Scale (PANSS) at baseline and 2 months after treatment

Key secondary outcome(s)

Measured before treatment and 2 months after treatment:

1. Anxiety and depression measured using the Hamilton Anxiety Rating Scale (HAMA) and the Hamilton Depression Rating Scale (HAMD)
2. Severity of trauma exposure measured using the Traumatic Exposure Severity Scale (TESS)
3. Severity of disease measured using the Brief Psychiatric Rating Scale (BPRS)
4. Memory measured using the Wechsler Memory Scale (WMS)

Completion date

01/03/2020

Eligibility**Key inclusion criteria**

1. Aged >18 years old
2. With complete medical records
3. With Positive and Negative Syndrome Scale (PANSS) scores for both positive and negative symptoms >60 points
4. With a clinical diagnosis of TRS
5. Who had had TRS for >5 years
6. Who had had previous treatment with 2 or more antipsychotic drugs of different chemical structure, each at a sufficient dosage, with no significant improvement after continuous treatment for more than 2 months
7. Those who did not show drug intolerance or maladaptation during the course of this study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

108

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/01/2018

Date of final enrolment

31/12/2019

Locations

Countries of recruitment

China

Study participating centre**Wuhan Wudong Hospital**

No. 46 Wudong Street

Qingshan District

Wuhan

China

430084

Sponsor information

Organisation

Wuhan Wudong Hospital

ROR

<https://ror.org/00qtzg544>

Funder(s)

Funder type

Government

Funder Name

Wuhan Municipal Health Commission (grant number NO.WX17C20)

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date