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

Submission date
27/02/2024

Recruitment status
No longer recruiting

Registration date
11/03/2024

Overall study status
Completed

Last Edited
08/03/2024

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
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
Dr Qiu-Ming Ji

Contact details
No. 46 of Wudong Street
Qingshan District
Wuhan
China
430084
+86 (0)27 5052 8367
jiqiuming79@163.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Pharmaceutical study type(s)
Pharmacodynamic

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Risperidone, Thymatron® System IV, atropine, propofol, succinylcholine chloride

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

Secondary outcome measures
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)

Overall study start date
01/07/2017

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
108

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

Sponsor details
No. 46 of Wudong Street
Qingshan District

Wuhan
China
430084
+86 (0)27 86438247
jiqiuming79@163.com

Sponsor type
Hospital/treatment centre

Website
http://www.wdyy.com/

ROR
https://ror.org/00qtzg544

Funder(s)

Funder type
Government

Funder Name
Wuhan Municipal Health Commission (grant number NO.WX17C20)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
12/12/2024

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