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Study on the precise treatment of schizophrenia patients in the subgroup of blunted niacin response

Submission date
19/12/2023

Recruitment status
No longer recruiting

Registration date
29/12/2023

Overall study status
Completed

Last Edited
28/12/2023

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 complex disorder that presents long-term challenges such as a lack of objective diagnostic markers and complex and varying clinical symptoms. The blunted niacin skin flushing response is commonly observed in patients with schizophrenia and is considered one of the objective diagnostic markers for the disorder. It is closely related to the membrane lipid disorder hypothesis of schizophrenia, which suggests that schizophrenia subgroups selected based on blunted niacin response are believed to be caused by membrane lipid disorders. Factors leading to membrane lipid disorders in the body include lipid peroxidation caused by oxidative stress and inflammatory responses. Fish oil is a common antioxidant and anti-inflammatory supplement, composed mainly of n-3 polyunsaturated fatty acids, which are important components of membrane lipids. Therefore, in this study, the aim is to select schizophrenia patients with dulling niacin reaction based on the participants' skin niacin reaction, and provide them with a one-cycle treatment of fish oil supplementation while maintaining regular clinical treatment. The auxiliary therapeutic effect of fish oil on the niacin dulling subgroup of schizophrenia patients will be evaluated through an assessment of their clinical symptoms and cognitive abilities.

Who can participate?
Patients aged between 18 and 65 years with schizophrenia who are registered at Renmin Hospital of Wuhan University, and eligible healthy volunteers

What does the study involve?
The patients were randomly recruited in the hospital outpatient department and were divided into blunted and normal niacin response groups according to their niacin skin flushing responses. The blunted niacin response group was supplemented with fish oil, and the supplementation cycle was one treatment cycle, that is, continued until the patient's next visit to the hospital for routine follow-up treatment. The supplemental dose of fish oil (Puritan’s Pride OMEGA-3 Fish Oil, USA) is 1800-2700 mg per day. Niacin response and Brief Assessment of Cognition in Schizophrenia (BACS) were administered to all subjects before treatment (baseline) by trained psychiatrists, and all patients were assessed with the Positive and Negative Syndrome Scale

(PANSS). At follow-up, niacin response and the BACS and PANSS scales were assessed in fish oil supplementation patients.

What are the possible benefits and risks of participating?
All participants have access to a clinical evaluation by the professional psychiatrists, which is free of charge. And participants who receive the PUFA may benefit from a reduction of their psychiatric symptoms. There are no known risks involved with participating.

Where is the study run from?
Renmin Hospital of Wuhan University (China)

When is the study starting and how long is it expected to run for?
January 2019 to December 2023

Who is funding the study?
National Natural Science Foundation of China

Who is the main contact?
1. Shijing Wang, wdrmiit@163.com
2. Dandan Wang, wangdandan26@126.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Mr Shijing Wang

Contact details
238 Jiefang Road, Renmin Hospital of Wuhan University
Wuhan
China
430000
+86 (0)18077408842
wdrmiit@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
Effects of fish oil supplementation on niacin skin flushing responses, psychotic symptoms and cognition in the subgroup of schizophrenia patients with blunted niacin responses

Study objectives
Blunted niacin response is widely shown in patients with schizophrenia, which has become an objective auxiliary diagnostic marker for schizophrenia and is closely related to the pathological hypothesis of abnormal membrane phospholipids in schizophrenia. The main component of fish oil is n-3 polyunsaturated fatty acid, which plays an important physiological role in regulating membrane phospholipids. This study aims to identify schizophrenia patients with impaired niacin response and administer fish oil supplementation as a targeted intervention, ultimately shedding light on the potential of niacin flush response as a guide for clinical schizophrenia treatment and prognostic indicators.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/05/2019, Ethics Committee of Bio-X Institutes at Shanghai Jiao Tong University (Shanghai, Huashan Road, Shanghai, 200030, China; +86 (0)15921495069; wangdandan26@126.com), ref: ML2019041

Study design
Single-center interventional open-label randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Interventions
Recruited patients are tested for niacin skin flushing responses and divided into blunted and normal niacin response groups according to their niacin skin flushing responses. Subsequently, patients with blunted niacin responses are randomly were randomly assigned to receive fish oil supplementation for 3 months. Those not randomly assigned were not given fish oil

supplementation. The method of randomisation is according to a computer-generated random sequence using block randomisation with random block sizes. The randomisation is performed by the independent statistician. Patients are enrolled and assigned sequentially to adjuvant interventions by the physician. The allocation sequence is not available to any member of the research team until the databases had been completed and locked.

The supplemental dose of fish oil (Puritan’s Pride OMEGA-3 Fish Oil, USA) is 1800-2700 mg per day.

Niacin response and Brief Assessment of Cognition in Schizophrenia (BACS) were administered to all subjects before treatment (baseline) by trained psychiatrists, and all patients were assessed with the Positive and Negative Syndrome Scale (PANSS). At follow-up, niacin response, BACS and PANSS scales were assessed in fish oil supplementation patients.

Intervention Type
Supplement

Primary outcome measure
Psychotic symptoms measured using the Positive and Negative Syndrome Scale were measured at baseline and month 3

Secondary outcome measures
1. Niacin skin flushing response were measured at baseline and month 3
2. Cognition measured using the Brief Assessment of Cognition in Schizophrenia were measured at baseline and month 3

Overall study start date
01/01/2019

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Patients with schizophrenia diagnosed according to Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria
2. Age between 18 and 65 years
3. Commitment to comply with the study procedures and cooperate with the implementation of the entire research process

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
138 = 96 patients with normal niacin response, and 42 patients with blunted niacin response requiring fish oil supplement

Total final enrolment
138

Key exclusion criteria
1. Severe neurological diseases or traumatic brain injury
2. Substance dependence
3. Administration of nonsteroidal or steroidal anti-inflammatory drugs within 2 weeks
4. Having a history of severe allergies, currently suffering from skin diseases or immune system diseases
5. Pregnancy

Date of first enrolment
01/06/2019

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
China

Study participating centre
Renmin Hospital of Wuhan University
238 Jiefang Road
Wuhan
China
430000

Sponsor information

Organisation
Renmin Hospital of Wuhan University

Sponsor details

238 Jiefang Road
Wuhan
China
430000
+86 (0)138 8602 9165
hlwang@whu.edu.cn

Sponsor type
Hospital/treatment centre

Website
http://www.rmhospital.com/

ROR
https://ror.org/03ekhbz91

Funder(s)

Funder type
Research organisation

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

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

Intention to publish date
01/06/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Shijing Wang (wdrmiit@163.com). The data will be available beginning 3 months and ending 5
years following article publication. It can be shared with researchers who provide a methodologically sound proposal to achieve the aims in the approved proposal. To gain access, data requesters will need to sign a data access agreement. Consent from participants was obtained. Data will be de-identified by removing personally identifiable information.

IPD sharing plan summary

Available on request