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Open trial addition of divalproex sodium in improving the symptoms of Batak and Non Batak males with schizophrenia in North Sumatra, Indonesia

Submission date
31/01/2019

Recruitment status
No longer recruiting

Registration date
06/03/2019

Overall study status
Completed

Last Edited
06/03/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Ethnicity is one of many factors that influence the drug response in patients with schizophrenia. In North Sumatra, Indonesia, information on the effect of divalproex sodium in patients from the Batak and non-Batak tribes is very limited. The aim of this study is to investigate differences in symptoms between Batak and non-Batak males with schizophrenia between those who received risperidone treatment with addition of divalproex sodium and those who only received risperidone treatment.

Who can participate?
Male patients aged 20-45 with schizophrenia from the Batak and non-Batak tribes

What does the study involve?
Participants are randomly allocated to be treated with risperidone and divalproex sodium or only risperidone. Before getting treatment both groups' schizophrenia symptoms are assessed and they undergo weight measurement, routine blood tests and liver function tests. The group receiving risperidone with sodium divalroex receive a dose of sodium divalproex once a day at night, increasing from from 500 mg/day on the first day, to 1000 mg/day on the fourth day, and on the seventh day increasing to 1500 mg/day, then the dose is maintained until the observation at the end of the sixth week. The dose of risperidone is given in divided doses twice per day, increasing from 4 mg/day on the first day, to 5 mg/day on the fourth day, and to 6 mg/day on the seventh day, then the dose is maintained until the observation at the end of the sixth week. Follow-up is done every week by assessing symptoms in each group. Observation of drug side effects such as gastrointestinal complaints and tremor is also observed every day every week, while weight measurements and routine blood tests of liver function are performed again at the end of the sixth week.

What are the possible benefits and risks of participating?
Participating could lead to decreased schizophrenia symptoms. The side effects from sodium

divalproex may include gastro intestinal, extra pyramidal syndrome and increasing of liver function.

Where is the study run from?
Mental Hospital Prof. Dr. M. Ildrem Medan, North Sumatra (Indonesia)

When is the study starting and how long is it expected to run for?
August 2014 to February 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mrs Novi Prasanty
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
N/A

Study information

Scientific Title

Addition of divalproex sodium in improving the symptoms of Batak and Non Batak males with schizophrenia in North Sumatra, Indonesia

Study objectives
There is a significant different in schizophrenia symptoms of Batak and Non-Batak Male Patients In North Sumatra, Indonesia between divalproex sodium with risperidone treatment and with risperidone only.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health Research Ethical Committee, Medical Faculty of Universitas Sumatera Utara/H. Adam Malik General Hospital, Jl. Dr. Mansyur No 5 Medan, 20155, Indonesia, Tel: +62 (0)61 8211045, 8210555, Email: komisietikfkusu@yahoo.com, 07/09/2017, ref: 507/KEPK FK USU-RSUP HAM /2017

Study design
Open trial experiment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Batak and Non-Batak male patients with schizophrenia

Interventions
Sampling was done by non-probability type consecutive sampling. Each subject who has been willing to be the subject of research and has signed a research agreement will be selected to meet the inclusion and exclusion criteria and will be grouped according to ethnicity. The interventions in this study were conducted using the open trial method, where researchers and research subjects in this study both knew of the interventions given to each group of subject subjects, according to those grouped first based on the Batak and Non Batak tribes. After collecting based on tribal grouping, the subjects for the intervention group were those who received risperidone and sodium divalproex, as well as subjects for the group who only received risperidone. The allocation for each intervention group was taken using a simple random sampling method; where each subject was present having the same opportunity. It is because of the number of samples in this study was small, namely 60 subjects, which consisted of 30 subjects for the Batak tribe and 30 subjects for the Non Batak tribe. Each ethnic group will be divided into two intervention groups, namely 15 subjects as the intervention group who received risperidone therapy with the addition of sodium divalproex and 15 subjects only receiving risperidone therapy. Then, the subject allocation for each intervention group is only done by drawing, namely with the following steps: for each tribe group, prepared paper numbered 1 to 30 and two boxes as containers. Then the numbered paper is rolled and scrambled. The scrambled paper is then randomly drawn and drawn to be placed in each box A (totalling 15) and box B (totalling 15). Box A is the intervention group that received risperidone therapy with the addition of divalproex and box B sodium is the group that only received

risperidone therapy. Next is the data collection of the existing numbers in each box. Each subject that comes in has been grouped by tribe, will get an intervention in accordance with the sequence number when the subject comes, and the sequence number will be adjusted again to the data number that is in each box.

1. Risperidone (6 mg) with the addition of divalproex sodium (1500 mg)
2. Risperidone (6 mg) only

Before getting treatment, either the intervention group that receive risperidone and sodium divalproex or the group that only receive risperidone in each ethnic group, measured the PANSS score first. Each subject will also undergo weight measurement, routine blood tests and liver function tests. This data will later become the baseline data (week 0) before getting the intervention.

The group receiving risperidone with sodium divalroex received a dose of sodium divalproex once a day at night, which was titrated from 500 mg/day on the first day, then raised to 1000 mg /day on the fourth day, and on the seventh day it was raised to 1500 mg/day, then the dose is maintained until the observation at the end of the sixth week. The dose of risperidone is given in divided doses twice administration/day, which is titrated from 4 mg/day on the first day, then raised to 5 mg/day on the fourth day, and on the seventh day is increased to 6 mg/day, then the dose is maintained until the observation at the end of the sixth week.

Follow-up is done every week by seeing a decrease in symptoms from each group, as measured by the PANSS score, which is also an indicator of treatment progress. Observation of drug side effects such as gastrointestinal complaints, tremor is also observed every day every week, while weight measurements and routine blood tests of liver function will be performed again after observation 6 weeks at the end of the sixth week. The study is on treatment analysis, and then the subjects who drop out will then be issued in the study, and will be replaced with a new subject so that it continues to meet the set sample size. Drop out criteria are subjects who are not adherent to treatment, resign, or have side effects from the treatment.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Divalproex sodium, risperidone

Primary outcome(s)
Schizophrenia symptoms measured using PANSS scores at baseline and every weeks for 6 weeks

Key secondary outcome(s))
Adverse effects such as gastrointestinal complaints, tremor observed every day every week for 6 weeks

Completion date
26/02/2018

Eligibility

Key inclusion criteria
1. Age range of 20-45 years
2. Schizophrenia for over 2 years
3. PANSS total score between 80-150 (acute phase of treatment)
4. Body weight < 65 kg

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. PANSS Excited Component (PANSS EC) >20
2. History of chronic medical disease
3. History of substance use (except caffeine and nicotine)

Date of first enrolment
11/09/2017

Date of final enrolment
22/01/2018

Locations

Countries of recruitment
Indonesia

Study participating centre
Mental Hospital Prof. Dr. M. Ildrem Medan, North Sumatra
Jl. Tali Air No 2, Mangga, Medan Tuntungan
Medan
Indonesia
20141

Sponsor information

Organisation

University of Sumatera Utara

ROR
https://ror.org/01kknrc90

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Novi Prasanty (noviprasanty86@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		21/02/2019	06/03/2019	No	No