ISRCTN06123818 https://doi.org/10.1186/ISRCTN06123818

Study of lymphocyte neurotransmitter markers in depression and anxiety

Submission date	Recruitment status
31/01/2008	No longer recruiting
Registration date	**Overall study status**
27/06/2008	Completed
Last Edited	**Condition category**
11/06/2019	Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Lucimey Lima

Contact details
Laboratorio de Neuroquímica
Instituto Venezolano de Investigaciones Científicas
Carretera Panamericana Km 11
Apdo. 21827
Caracas
Venezuela
1020-A
+58 212 504 1213
llima@ivic.ve

Additional identifiers

Protocol serial number
FONACIT G-1387

Study information

Scientific Title

A randomised study on the antidepressive effect of fluoxetine and folic acid, as possible augmenter, and the SYNThesis of serotonin (5-HT) in lymphocytes prior and after treatment

Acronym
5HTSYNT

Study objectives
The administration of folic acid plus the antidepressant fluoxetine to patients with major depression could augment the response to the antidepressant, and also modify the content, the synthesis of serotonin, neurotransmitter and immunomodulator, and the presence of tryptophan hydroxylase in lymphocytes, and then influence functionality

Ethics approval required
Old ethics approval format

Ethics approval(s)
This trial was part of a project "Nervous System Markers in Lymphocytes of Patients with Major Depression or Generalized Anxiety." This project received approval from three ethics committees:
1. Ethic Committees of the Venezuelan Institute of Scientific Invesgigations (Instituto Venezolano de Investigaciones Científicas; IVIC). Approved in 2000
2. Caracas Hospital (Hospital Vargas de Caracas; VHC). Approved in 2001
3. The National Fund of Scientific Technology and Innovation (FONACIT; http://www.fonacit.gov.ve). Approved in 2001

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Major depression

Interventions
As of 22/07/2008, information on the dose and route of administration for each drug /supplement were added to the interventions:
This trial consists of two studies:
Study 1: Fluoxetine (oral) 20 mg/day plus placebo (30 participants) vs fluoxetine (oral) 20 mg/day plus omega-3 (oral) 900 mg/day (30 participants)
Study 2: Fluoxetine (oral) 20 mg/day plus placebo (30 participants) vs fluoxetine (oral) 20 mg/day plus folic acid (oral) 10 mg/day (30 participants)

Total number of participants = 30 x 4 = 120

Interventions provided at time of registration:
This trial consists of two studies:

Study 1: Fluoxetine plus placebo (30 participants) vs fluoxetine plus omega-3 (30 participants)
Study 2: Fluoxetine plus placebo (30 participants) vs fluoxetine plus folic acid (30 participants)

Total number of participants = 30 x 4 = 120 participants.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
fluoxetine and folic acid

Primary outcome(s)
1. Response to differential treatment at 2, 4 and 6 weeks
2. Magnitude of the response at 2, 4 and 6 weeks
3. Biochemical analyses on blood samples at 0 and 6 weeks:
3.1. Neurotransmitters in plasma
3.2. Isolation of lymphocytes
3.3. Neurotransmitters in lymphocytes
3.4. Detection of tryptophan hydroxylase
3.5. Folate levels
3.6. Homocysteine levels
3.7. Vitamin B12 levels
4. In participants who took omega-3, brain-derived neurotrophic factor (BDNF) in serum and lymphocytes will be determined

Key secondary outcome(s)
Correlation between response to antidepressant and biochemical measurements

Completion date
29/02/2008

Eligibility

Key inclusion criteria
1. Both males and females
2. 18 to 60 years
3. Major depression episode, according to the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) criteria
4. Without psychotic symptoms
5. Mild and moderate
6. Without risks of suicide
7. Without another psychiatric disorder
8. Without another medical illness
9. Free of pharmacological treatment for one month prior to inclusion into the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
27

Key exclusion criteria
1. Pregnancy
2. Surgery
3. Adverse effect to treatments
4. Allergies, infections, inflammation
5. Excessive consumption of coffee, tea, tobacco or alcohol

Date of first enrolment
01/12/2006

Date of final enrolment
29/02/2008

Locations

Countries of recruitment
Venezuela

Study participating centre
Laboratorio de Neuroquímica
Caracas
Venezuela
1020-A

Sponsor information

Organisation
Venezuelan Institute of Scientific Investigations (Instituto Venezolano de Investigaciones Científicas) (Venezuela)

ROR
https://ror.org/02ntheh91

Funder(s)

Funder type
Government

Funder Name
The National Fund of Scientific Technology and Innovation (FONACIT; ref: G-1387) (Venezuela)

Funder Name
The Venezuelan Institute of Scientific Investigations (IVIC) (Venezuela)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2008	11/06/2019	Yes	No