

# Study of lymphocyte neurotransmitter markers in depression and anxiety

<b>Submission date</b> 31/01/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/06/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## 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 augmenters, 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 Investigations (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

## **Study design**

Randomised controlled trial

## **Primary study design**

Interventional

## **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 =  $30 \times 4 = 120$

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 =  $30 \times 4 = 120$  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?
<a href="#">Results article</a>	results	01/07/2008	11/06/2019	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes