ISRCTN11216093 https://doi.org/10.1186/ISRCTN11216093

Changes in plasma and platelet Brain-Derived Neurotrophic Factor (BDNF) levels induced by S-citalopram in major depression

Submission date 17/05/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/06/2010	**Overall study status** Completed	
Last Edited 23/06/2010	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Montserrat Serra

Contact details
Canigó 51, 6B
Vic
Spain
08500

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Utility of serum and platelet levels of Brain- Derived Neurotrofic Factor (BDNF) like biological marker of treatment response in major depression: a longitudinal controlled trial

Acronym
BDNF

Study objectives
1. BDNF levels in depressed patients are lower than in healthy controls in platelet poor plasma and in platelets
2. 8 and 24 weeks treatment with S-citalopram normalize BDNF levels to be similar to healthy controls

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Hospital Clinic of Barcelona approved in March 2005

Study design
Longitudinal controlled study for 6 months

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please contact Mrs Montserrat Serra Millàs [serra2mont@yahoo.es] to request a patient information sheet

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

Interventions
Patients group:
After the baseline assessments and baseline blood samples were obtained, all patients were given S-citalopram orally as an antidepressant therapy. Beginning with 5 mg/day for 4 days, and increased to 10 mg/day in the fifth day. In the following visits, the psychiatrist increased the doses as required up to a maximum of 40 mg/day. We used elevated doses based on severity of clinical depression and on personal experience. One doses per day. The duration of follow-up was 6 months.

Healthy controls:
Assessments at baseline and no treatment.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
S-citalopram

Primary outcome measure
BDNF levels in platelets and plasma, measured at baseline, 8 and 24 weeks of treatment in the patient group, once in the control group

Secondary outcome measures
1. Severity of depression was assessed using the 17-item Hamilton Depression Rating Scale (HDRS)
2. Cognitive performance, assessed by:
2.1. Wechsler Adult Intelligence Scale (WAIS-III): Vocabulary, Buckets of Kohs, numerical key similitudes
2.2. Wechsler Memory Scale (WMS-III): Digits, Verbal Memory I, Verbal Memory II
2.3. Train Making Test (TMT) part A and B
2.4. Auditory Verbal Learning Test (AVLT de Rey) (Rey 1964)
2.5. Stroop Color and Word Test
2.6. Wisconsin Card Sorting Test (WCST)
3. Quality of life scales:
3.1. Social Adaptation Self-evaluation Scalen (SASS)
3.2. Perceived Stress Scale (PSS)
3.3. Quality of Life in Depression Scale (QLDS)
4. Personality, assessed by Eysenck Personality Questionnaire (EPQ)

Clinical assessments were conducted at baseline, 2, 4, 8, 12, 16, 20 and 24 weeks of treatment, once in the control group.

Overall study start date
01/07/2005

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Patient group:
1.1. Patients suffering from a current major depressive episode, single episode or recurrent, diagnosed according to Diagnostic and Statistical Manual for Mental Disorders Criteria
1.2. A 17-item Hamilton Depression Rating Scale (HDRS) total score of 18 or higher.

1.3. Aged between 18 and 65 years
2. Control group:
2.1. Healthy subjects with no history of chronic physical illness, substance abuse or mental diseases and not taking regular medications in the last month were recruited
2.2. Free of chronic and acute physical illness within the 2 weeks before the study
2.3. Aged between 18 and 65 years
3. Written information was given and written informed consent was obtained from each patient to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
32 participants (18 depressive patients and 14 healthy controls)

Key exclusion criteria
1. Patient group:
1.1. Presence of other major axis I disorders, including schizophrenia, bipolar disorders, anxiety disorders, substance-related disorders and eating disorders
1.2. Presence of any acute physical disorders and/or exposure to any psychotropic drugs in the last month
2. Control group
2.1. History of chronic physical illness, substance abuse or mental diseases or taking regular medications in the last month
2.2. Free of chronic and acute physical illness within the 2 weeks before the study

Date of first enrolment
01/07/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Spain

Study participating centre
Canigó 51, 6B
Vic

Spain
08500

Sponsor information

Organisation
Hospital Clinic of Barcelona (Hospital Clínic de Barcelona) (Spain)

Sponsor details
Villarroel 170
Barcelona
Spain
08036

Sponsor type
Hospital/treatment centre

Website
http://www.hospitalclinic.org

ROR
https://ror.org/02a2kzf50

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Clinic of Barcelona (Beca fi de residència Hospital Clínica) (Spain) - Grant

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration