International Study for the Prediction of Optimized Treatment - in Depression

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Observational invasive

Summary

ID

NL-OMON32293

Source
ToetsingOnline

Brief title
iSPOT-D

Condition

- Mood disorders and disturbances NEC

Synonym
depression, major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Brain Resource Company
Source(s) of monetary or material Support: Brain Resource Company Operations

Intervention

Keyword: Depression, neuropsychology, Personalized Medicine, QEEG

Outcome measures

Primary outcome

In order to answers the studys' objectives, profiles of genetic, psychological,

cognitive and

brain markers will be used (for details see protocol page 21 and further)

- Psychological test markers: number of stressful events

- Cognitive test markers: Scores are performance scores in each test: including

accuracy and reaction time. Factor scores will also be derived for the

composite domains.

- Electrical Brain Function markers: EEG Power in the four frequency bands,

delta, theta, alpha and beta, EEG Asymmetry,

EEG synchrony, ERP amplitudes and latencies for the components of key interest

in a variety of tasks.

- Heart rate and Heart rate variability will be quantified

- Skin Conductance

- EMG responses to each startle/prepulse stimulus

- Genetic markers (a variety of targets see protocol page 27)

Secondary outcome

n.v.t.

Study description

Background summary

MDD is projected to cause the second greatest global burden of disease by 2020, highlighting the urgent need for valid predictors of effective treatment response. Currently, there are no accurate predictors of response to antidepressants in MDD, and successful treatment relies greatly on 'trial and error'. The aim of this study is to identify genetic, brain and cognitive assessment/test results that statistically correlate to and predict a treatment response (further referred to as 'markers') to the three most commonly used antidepressants (Escitalopram, Sertraline and Venlafaxine XR,) in subjects diagnosed with major depressive
disorder (MDD).

Study objective

The overall objectives of the iSPOT-D trial are to use standardised genetic-brain-cognition
protocols to:
1. Identify markers of MDD as a diagnostic group and its subtypes
2. Identify markers which change with acute (8 weeks) drug treatment in MDD
3. Identify predictors of treatment response in MDD, and types of response
4. To determine whether distinct individual characteristics in MDD subjects predict degree of
response to different treatment with different medications
Secondary questions will also be explored systematically within each of the above objectives:
1. Whether the markers of MDD and its sub-types also distinguish clusters of comorbid
conditions in MDD.
2. Whether the extent of change in markers with treatment is associated with other
subject*s characteristics, such as age and sex.
3. If markers which predict severity and response to treatment, also predict other aspects
of drug response, such as number of side effects.

Study design

This is an open-label, Randomised (effectiveness) study (ie. comparison of active treatments)
to identify genetic markers, brain function, brain structure, and psychological and cognitive
indicators (or a combination of markers) in MDD subjects versus healthy controls.
Approximately 2,016 subjects with major depressive disorder (MDD) across multiple

international sites will be randomised to one of three approved and effective treatment arms:
Treatment A Escitalopram.
Treatment B Sertraline.
Treatment C Venlafaxine XR.
A group of matched healthy controls (n = 672) will also be enrolled. Healthy control subjects will be matched to enrolled MDD subjects.

Study burden and risks

Time investment for the participant includes:
- screening measures (140 minutes): blood draw, pregnancy test, tox screen, psychiatric interview
- baseline assessment (200 minutes): a variety of questionnaires, neuropsychological test battery, neurophysiological test battery
- Clinical monitoring (8 x 10 mintues = 80 minutes): telephone interview, questionnaires
- Week 8 assessment (350 minutes): blood draw, questionnaires, neuropsychological test battery, neurophysiological (qEEG) test battery

Participation requires at least two visits to the clinics and 8 telephone interviews. Participants get paid 280 euro for participation.

Blood draw can be associated with local pain, bruising, occasional lightheadedness, fainting, and very rarely, infection at the site of the blood draw.The group of subjects with MDD will receive treatment with one of three registered medication (treatment as usual). Subjects can experience known side-effects of medication.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

meet DSM-IV criteria for primary diagnosis of MDD (patients), HAMD score>16 (patients), age between 18-65, Dutch fluency (patients and healty controls) signed a written informed consent (patients and health controls)

Exclusion criteria

1) presence of bipolar disorder, psychosis or primary eating disorders (patients) or current or previous diagnosis of MDD or other Axis 1 disorder (healthy controls) 2) pregnancy and women of child bearing potential who are not taking a medically accepted form of contraception and are at risk of becoming pregnant during the study, 3) breastfeeding, 4) presence of contra-indication of usage of Escitalopram, Sertraline or Venlafaxine XR (patients) 5) usage of any antidepressant or CNS drug which can not be washed out prior to participation 6) use of any medication which is known to be contraindicated with Escitalopram, Sertraline, or Venlafaxine XR 7)evidence of either hyper or hypo-thyroidism within previous 3 months, 8) known medical condition, disease or neurological disorder which might, in the opinion of the investigator, interfere with the assessments to be made in the study or put subjects at increased risk when exposed to optimal doses of the drug treatment, 9) personal history of physical brain injury or blow to the head that resulted in loss of consciousness of greater than five minutes, 10) recent/current substance dependence in accordance with current ABS criteria in the past 6 months, 11) participation in an investigational study within four months of the baseline visit in which subjects have received an experimental drug/device that could affect the primary end points of this study, 12)subjects who, in the opininon of the investigator, have a severe impediment to vision, hearing and/or hand movement, which is likely to interfere wiht their ability to complete the testing batteries, 13) subjects who, in the opininon of the investigator, are unable and/or unlikely to comprehend and follow the study procedures and instructions.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-12-2008
Enrollment:	500
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Efexor XR
Generic name:	Venlafaxine XR hydrochloride
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Lexapro
Generic name:	Escitalopram
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Zoloft
Generic name:	Sertraline
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	04-08-2008
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	18-02-2009
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	13-12-2011
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2008-004122-17-NL
CCMO	NL23574.072.08

Study results

Date completed:	01-05-2019
Results posted:	23-05-2019
Actual enrolment:	112

Summary results
Trial is onging in other countries

First publication
01-01-1900