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The prediction of short-term and long-term treatment response to sertraline in panic disorder

Submission date	Recruitment status	[ ] Prospectively registered
22/11/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/11/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/12/2006	Mental and Behavioural Disorders	[ ] Record updated in last year

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
STL-NL-96-002

Study information

Scientific Title

Study objectives
Baseline variables such as harm avoidance and other personality, biological and electrophysiological measures will predict treatment outcome to an Selective Serotonin Reuptake Inhibitor (SSRI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Panic disorder

Interventions
Intervention:
Treatment with Sertraline (50 mg) for a period of 57 weeks

Investigators Assessments:
Hamilton Anxiety Scale
Hamilton Depression Scale
Clinical Global Impression

Subjects assessments:
Frequency of panic attacks
Fear Questionnaire
Patient Global Evaluation
Symptoms CheckList (SCL-90)
Temperament and Character Inventory
NEO-Neuroticism subscale
Rand 36-item health survey
Rosenberg Self-esteem list

Biochemical assessments:
Plasma 3-Methoxy-4-HydroxyPhenylGlycol (MHPG) level
Plasma Sertraline level

Electrophysiology:
Heart Rate Variability

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Sertraline

Primary outcome(s)
To identify variables mentioned above (at baseline) that can predict short-term and long-term response to treatment with sertraline in Panic Disorder.

Key secondary outcome(s))
1. To establish whether Autonomous Nervous System (ANS) functioning is a state marker of illness severity.
2. To establish whether treatment with sertraline has an affect on the functioning of the ANS.

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Panic Disorder According to Diagnostic and Statistical Manual of mental disorders (DSM-IV)
2. Two panic attacks in medication-free run-in period
3. Outpatients more than 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

Key exclusion criteria
1. Co-morbid psychotic disorder, alcohol abuse, major affective disorder or personality disorder in the last year
2. Participation in other drug trial 30 days prior to selection
3. Serious medical illness
4. History of hepatitis
5. Risk of suicidality
6. History of drug allergy of hypersensitivity to SSRIs
7. Pregnancy, lactation or childbearing potential during the study

Date of first enrolment

01/06/2002

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
Rotterdam
Netherlands
9700 RB

Sponsor information

Organisation
University Medical Center Groningen (The Netherlands)

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Industry

Funder Name
Pfizer

Alternative Name(s)
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen, Pfizer Inc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary