

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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.

Overall study start date

01/06/2002

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

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

57

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 or 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)

Sponsor details

Room 5.29

Department of Psychiatry

P.O. Box 30001

Groningen

Netherlands
9700 RB

Sponsor type

Hospital/treatment centre

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

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

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