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

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Baseline variables such as Harm Avoidance and other personality, biological and electrophysiological measures will predict treatment outocme to an SSRI.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21722

Bron
NTR

Verkorte titel
N/A

Aandoening

Outpatient study at the University Outpatient Clinic, Department of Psychiatry Groningen.

Ondersteuning

Primaire sponsor: Pfizer

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

Phase I:

This phase starts with a 2-week no-treatment run-in period.

Phase II:

Open-label treatment with Sertraline of three months (until visit 7, day 85). Non-responders to short-term treatment with Sertraline will discontinue from the study at this point.

Phase III:

All other patients will be treated for 6 month and will enter a gradual drug taper, based upon clinical judgement.

Phase IV:

From visit 9 onwards, after drug taper-off, treatment will be naturalistic. At visit 10 (day 3666) a clinical follow-up evaluation will be performed.

Doel van het onderzoek

Baseline variables such as Harm Avoidance and other personality, biological and electrophysiological measures will predict treatment outocme to an SSRI.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Treatment with Sertraline (50 mg) for a period of 57 weeks.

Investigators Assessments:

1. Hamilton Anxiety Scale;

2. Hamilton Depression Scale,
3.Clinical Global Impression.

Subjects assessments:

1. Frequency of panic attacks;

2. Fear Questionnaire;

3. Patient Global Evlauation;

4. SCL-90;

5. Temperament and Character Inventory;

6. NEO-Neuroticism subscale;

7. Rand 36-item health survey;

8. Rosenberg Self-esteem list.

Biochemical assessments:

1. Plasma MHPG level, Plasma Sertraline level;

2. Electrophysiology: Heart Rate Variability

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Panic Disorder According to DSM-IV.

2. 2 panic attacks in medication-free run-in period.

3. Outpatients >18yrs.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Comorbid psychotic disorder, alcolhol 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 SSRI's.

7. Pregnancy, lactation or childbearing potential during the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2002
Aantal proefpersonen:	57
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	22-08-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL743
NTR-old	NTR753
Ander register	: STL-NL-96-002
ISRCTN	ISRCTN03447252

Resultaten

Samenvatting resultaten

In preparation.