

Quetiapine versus sertraline as the pharmacological component in a standardised psychopharmacological and psychotherapeutic treatment of borderline personality disorder: a randomised, rater-blinded study

Submission date 01/08/2006	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 31/08/2006	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 05/09/2006	Condition category Mental and Behavioural Disorders	☐ Individual participant data
		☐ 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
D1449L00014

Study information

Scientific Title

Acronym

QuBor Study

Study objectives

The objective of this randomised, rater blinded study is to compare the efficacy of two currently frequently used substances, the Selective Serotonin Reuptake Inhibitors (SSRI) sertraline and the atypical neuroleptic quetiapine, in the treatment of borderline personality disorder. It is the hypothesis of this study that the atypical neuroleptic quetiapine favorably affects a broader spectrum of the borderline psychopathology than sertraline. The pharmacotherapy should be accompanied by psychotherapy that is based on the dialectical behavior therapy of Linehan. This study will contribute to optimising the medication therapy of borderline personality disorder with respect to efficiency and clarity.

The hypothesis regarding the efficacy comparison of quetiapine and sertraline is that quetiapine is significantly superior to treatment with SSRIs in the therapy of the following target symptoms: impulsivity, aggressiveness, self-inflicted injuries/self-harming and suicidal behavior.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval is pending from the University of Duesseldorf.

Primary study design

Interventional

Study design

Randomised, rater-blinded trial.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Borderline Personality Disorder

Interventions

Intervention group one: Quetiapin 50-800 mg per day orally over 24 weeks.

Intervention group two: Sertralin 25-200 mg per day orally also over 24 weeks.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Quetiapine and sertraline

Primary outcome(s)

The primary assessment instrument will be the Symptom Check List 90 (SCL-90R) and the primary outcome parameter will be the anger/hostility subscale of the SCL-90R.

Key secondary outcome(s)

1. Severity of affective symptoms
2. Anxiety and depressive symptoms
3. Psychotic or psychosis-like symptoms
4. Interpersonal problems
5. Duration of hospitalisation
6. Co-medication

Completion date

15/03/2009

Eligibility

Key inclusion criteria

1. Borderline personality disorder according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)
2. At least 18 years of age
3. Voluntary legal basis
4. Female
5. Written informed consent before entering the study
6. No relevant abnormalities in Electrocardiogram (ECG) and laboratory tests

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Lifetime diagnosis of schizophrenia or schizoaffective disorder according to DSM IV
2. Lifetime diagnosis of bipolar disorder according to DSM IV
3. Current severe major depressive episode according to DSM IV
4. Current severe somatic illness
5. Current psychotic disorder due to substance disorder or a general medical condition
6. Use of drugs that induce or inhibit the metabolising cytochrome 3A4 enzymes within two weeks prior to week zero and during the course of the study (e.g. inducers: phenytoin, carbamazepin, phenobarbital, rifampin, rifabutin, glucocorticoids, thioridazine and St. John's wort and inhibitors: ketokonazole [except for topical use], itraconazole, fluconazole,

erythromycin, fluvoxamin, nefadozone, troleandomycin, indinavir, nelfinavir, ritonavir and saquinavir)

Date of first enrolment

01/10/2006

Date of final enrolment

15/03/2009

Locations

Countries of recruitment

Germany

Study participating centre

Bergische Landstrasse 2

Duesseldorf

Germany

40629

Sponsor information

Organisation

University of Duesseldorf (Germany)

ROR

<https://ror.org/024z2rq82>

Funder(s)

Funder type

Industry

Funder Name

AstraZeneca

Alternative Name(s)

AstraZeneca PLC, Pearl Therapeutics, AZ

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary