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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	Recruitment status	[X] Prospectively registered
01/08/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/08/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/09/2006	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

Study design
Randomised, rater-blinded 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
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 measure
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.

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

Overall study start date
01/10/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
54

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)

Sponsor details
Faculty of Medicine
c/o Prof Dr Nuernberg
Universitaetsstrasse 1

Duesseldorf
Germany
40225

Sponsor type
University/education

Website
http://medfak.uniklinikum-duesseldorf.de/

ROR
https://ror.org/024z2rq82

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

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