ISRCTN83050762 https://doi.org/10.1186/ISRCTN83050762

Quetiapine augmentation of a serotonin reuptake inhibitor in treatment resistant obsessive-compulsive disorder: a multi-site, placebo-controlled study

Submission date
13/01/2005

Recruitment status
No longer recruiting

Registration date
13/01/2005

Overall study status
Completed

Last Edited
11/08/2008

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Dan J Stein

Contact details
MRC Research Unit on Anxiety Disorders
Department of Psychiatry
University of Stellenbosch
Cape Town
South Africa
7505
+27 (0)21 938 9161
djs2@sun.ac.za

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5077IL/9009

Study information

Scientific Title

Study objectives
Although serotonin reuptake inhibitors are effective in the treatment of obsessive-compulsive disorder (OCD), many patients fail to respond to these agents. Growing evidence from open-label and placebo-controlled trials suggests a role for augmentation of serotonin reuptake inhibitors (SRIs) with atypical antipsychotics in OCD. Quetiapine is generally well tolerated and previous open-label data has produced mixed results in OCD, and additional controlled data is needed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Obsessive-compulsive disorder

Interventions
Placebo-controlled, double-blind, flexible-dose augmentation with quetiapine of a serotonin reuptake inhibitor maintaned at the stable maximum tolerated dose.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Not provided at time of registration.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/05/2002

Completion date
01/11/2003

Eligibility

Key inclusion criteria
Subjects with obsessive-compulsive disorder who failed at least one trial (12 weeks duration, of which six weeks at maximum tolerated dose) of a serotonin reuptake inhibitor.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
42

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2002

Date of final enrolment
01/11/2003

Locations

Countries of recruitment
Canada

South Africa

Study participating centre
MRC Research Unit on Anxiety Disorders
Cape Town
South Africa
7505

Sponsor information

Organisation
AstraZeneca (South Africa)

Sponsor details
5 Leeuwkop Road
Sunninghill
Johannesburg
South Africa
2157

Sponsor type
Industry

ROR
https://ror.org/04r9x1a08

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca Pharmaceuticals (South Africa)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	24/01/2005		Yes	No