

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	<input type="checkbox"/> Prospectively registered
Registration date 13/01/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/08/2008	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

50771L/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 maintained 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