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

Submission date	Recruitment status No longer recruiting	Prospectively registered	
13/01/2005		☐ Protocol	
Registration date 13/01/2005	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited 11/08/2008	Condition category Mental and Behavioural Disorders	[] 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

Protocol serial number 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 openlabel 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

Study type(s)

Treatment

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(s)

Not provided at time of registration.

Key secondary outcome(s))

Not provided at time of registration.

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

Sponsor information

Organisation

AstraZeneca (South Africa)

ROR

7505

https://ror.org/04r9x1a08

Funder(s)

Funder type

Industry

Funder Name

AstraZeneca Pharmaceuticals (South Africa)

Results and Publications

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