ISRCTN75061806 https://doi.org/10.1186/ISRCTN75061806

Efficacy and safety of agomelatine (25-50 mg /day) for 12 weeks in patients with Generalized Anxiety Disorder

Submission date	Recruitment status	[X] Prospectively registered
04/07/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/08/2012	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2018	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration and not expected to be available in the future

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CL3-20098-078

Study information

Scientific Title
Efficacy and safety of agomelatine (25-50 mg/day) for 12 weeks in patients with Generalized Anxiety Disorder: a randomised controlled trial

Study objectives
To assess the efficacy of agomelatine compared to venlafaxine after treatment in non-depressed outpatients suffering from Generalized Anxiety Disorder (GAD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
12-week randomised double-blind two-arm parallel groups international multicenter study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Generalized Anxiety Disorder

Interventions
Therapeutic oral doses of agomelatine (25-50mg/day p.o.) and of Serotoninnorepinephrine reuptake inhibitors (SNRI), venlafaxine (p.o.), a 12 weeks study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
HAM-A total score expressed mainly in terms of change from baseline to last post-baseline value over the 12-week period.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2012

Completion date
31/07/2014

Eligibility

Key inclusion criteria
1. Asian patients aged 18 years
2. Fulfilling Diagnostic and Statistical Manual of Mental Disorders, fourth edition, text revision (DSM-IV-TR) criteria for Generalized Anxiety Disorder diagnosis confirmed by the M.I.N.I. questionnaire and requiring a psychotropic treatment.
3. Hamilton Anxiety Scale (HAM-A) total score >22

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
510

Key exclusion criteria
1. All types of current anxiety disorders (within 6 months prior to the selection visit) other than generalized anxiety disorder (GAD)
2. Current diagnosis of any other psychiatric disorders than GAD or severe or uncontrolled organic disease
3. Any clinically relevant abnormality detected during the physical examination, ECG, liver B ultrasound exams or laboratory tests likely to interfere with the study conduct or evaluations
4. Pregnancy or breastfeeding women

Date of first enrolment
01/11/2012

Date of final enrolment

31/07/2014

Locations

Countries of recruitment
China

Hong Kong

Malaysia

Singapore

Taiwan

Thailand

Study participating centre
Mental Health Institute
Changsha, Hunan, P.R.
China
410011

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

Sponsor details
50 rue Carnot
Suresnes
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Sponsor type
Industry

Website
http://www.servier.com/

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Publication and dissemination plan
Summary results are published in https://clinicaltrials.servier.com.
For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from https://clinicaltrials.servier.com if a Marketing Authorisation has been granted after 1st January 2014.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No