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

Contact name
Prof Jing Ping Zhao

Contact details
Mental Health Institute
The Second Xiangya Hospital of Central South University
No. 139, Renmin Middle Road
Changsha, Hunan, P.R.
China
410011
+86 0731 5360921
clinicaltrials@servier.com

Additional identifiers

Protocol serial number
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

Study type(s)
Screening

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(s)
HAM-A total score expressed mainly in terms of change from baseline to last post-baseline value over the 12-week period.

Key secondary outcome(s))
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes