

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

Submission date 04/07/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 07/08/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/04/2018	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 and not expected to be available in the future

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 Serotonin-norepinephrine 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.
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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