

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

France

92284

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