

Efficacy and safety of agomelatine for 12 weeks in non-depressed out-patients with Generalised Anxiety Disorder

Submission date 02/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/07/2010	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

2009-013789-17

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CL3-20098-071

Study information

Scientific Title

Efficacy and safety of agomelatine (25 mg/day with potential blinded adjustment to 50 mg/day) for 12 weeks in non-depressed out-patients with Generalised Anxiety Disorder

Study objectives

To confirm the superiority of agomelatine compared to placebo in treatment of non-depressed out-patients suffering from Generalised Anxiety Disorder (GAD).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Committee I. of Ethics in Clinical Trials (Comite I. de Etica para Ensayos en Farmacologia Clinica) of the University of Medicine at Buenos Aires approved on 26/11/2009

Study design

12-week randomised double blind placebo controlled with escitalopram as validator 3-arm parallel group international multicentre study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

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

Generalised Anxiety Disorder

Interventions

Agomelatine 25 or 50 mg versus placebo and escitalopram 10 or 20 mg

Intervention Type

Other

Phase

Phase III

Primary outcome measure

Hamilton Anxiety (HAM-A) total score, in the W0-W12 period (baseline to 12 weeks)

Secondary outcome measures

1. Hamilton Anxiety (HAM-A) items from baseline to W12 (week 12)
2. Clinical Global Impression Severity (CGI-S) and Clinical Global Impression Improvement (CGI-I) scores from baseline to W13
3. Hospital Anxiety Depression (HAD) sub-scores from baseline to W12
4. Self-rating Depression Scale (SDS) scores from baseline to W12
5. Leeds Sleep Evaluation Questionnaire (LSEQ) scores from W2 to W12
6. Safety from baseline to W12 (final visit)

Overall study start date

27/04/2010

Completion date

31/08/2011

Eligibility

Key inclusion criteria

1. Out-patients of both genders aged between 18 (or legal majority) and 65 years of age (inclusive)
2. Fulfilling American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition-Text Revision (DSM-IV-TR) criteria for GAD

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

390

Key exclusion criteria

1. Patients meeting DSM-IV-TR current diagnosis of psychiatric disorder other than GAD within 6 months prior to selection
2. Women of childbearing potential without effective contraception as well as pregnant or breastfeeding women
3. Any relevant clinical abnormality detected during physical examinations, ECG or laboratory tests likely to interfere with the study conduct or evaluations

Date of first enrolment

27/04/2010

Date of final enrolment

31/08/2011

Locations**Countries of recruitment**

Argentina

Czech Republic

Finland

Korea, South

Poland

Russian Federation

Slovakia

Study participating centre

Mehilainen Clinic

Helsinki

Finland

00260

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
Results article	results	01/04/2014		Yes	No