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

Submission date	Recruitment status	[ ] Prospectively registered
02/06/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/07/2010	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

Clinical Trials Information System (CTIS)
2009-013789-17

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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 Wend (final visit)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

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?
Results article	results	01/04/2014		Yes	No
Basic results				No	No