

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

|                                        |                                                               |                                                      |
|----------------------------------------|---------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>02/06/2010   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>05/07/2010 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>18/04/2018       | <b>Condition category</b><br>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

### 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 W12 (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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/04/2014   |            | Yes            | No              |
| <a href="#">Basic results</a>   |         |              |            | No             | No              |

