# 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

#### Contact name

Prof Antti Ahokas

#### 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 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** 

Slovakia

00260

Study participating centre Mehilainen Clinic Helsinki Finland

# 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	