Long-term efficacy and safety of agomelatine in non-depressed out-patients with generalized anxiety disorder. A 26-week randomised doubleblind placebo-controlled parallel group study following an open-label period of 16 weeks with agomelatine (25 mg/day with the possibility for blinded dose-adjustment to 50 mg /day)

Submission date	Recruitment status No longer recruiting	Prospectively registered		
24/09/2007		☐ Protocol		
Registration date 26/03/2008	Overall study status Completed Condition category	Statistical analysis plan		
		[X] Results		
Last Edited		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 Istvan Bitter

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2006-005674-47

Protocol serial number

CL3-20098-050

Study information

Scientific Title

Long-term efficacy and safety of agomelatine in non-depressed out-patients with Generalized Anxiety Disorder. A 26-week randomised double-blind placebo-controlled parallel group study following an open-label period of 16 weeks with agomelatine (25mg/day with the possibility for blinded dose-adjustment to 50mg/day).

Study objectives

To assess the efficacy of agomelatine in the prevention of relapse in non-depressed out-patients with Generalized Anxiety Disorder (GAD) after an initial response to agomelatine.

Ethics approval required

Old ethics approval format

Ethics approval(s)

First ethics committee approval in Estonia (Tallin Medical Research Ethics Committee) on 16/08 /2007 (ref: 1121)

Study design

Randomised double-blind parallel-group placebo-controlled multi-centre phase III study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Generalized anxiety disorder

Interventions

Agomelatine versus placebo

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Agomelatine

Primary outcome(s)

Time to relapse

Key secondary outcome(s))

- 1. Evaluation of anxiety (Hamilton rating scale for anxiety [HAM-A])
- 2. Safety

Completion date

15/03/2010

Eligibility

Key inclusion criteria

- 1. Aged over 18 years
- 2. Out-patients of both genders
- 3. Fulfilling the Diagnostic and Statistical Manual of mental disorders fourth edition (DSM-IV) 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. Women of childbearing potential without effective contraception
- 2. Patients meeting DSM-IV-TR current diagnosis of psychiatric disorder other than GAD
- 3. Any clinically relevant abnormality detected during the physical examination, ECG or laboratory tests likely to interfere with the study conduct or evaluations

Date of first enrolment

15/10/2007

Date of final enrolment

15/03/2010

Locations

Countries of recruitment

Canada

Denmark
Estonia
Finland
Hungary
Sweden
Study participating centre Department of Psychiatry and Psychotherapy Budapest Hungary 1083
Sponsor information
Sponsor information Organisation Institut de Recherches Internationales Servier (France)
Organisation
Organisation Institut de Recherches Internationales Servier (France) ROR

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 reviewe	d? Patient-facing?
Results article	results	01/07/2012	Yes	No
Basic results			No	No
Participant information sheet	Participant information sheet	11/11/2025 11/11	/2025 No	Yes