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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 (25 mg/day with the possibility for blinded dose-adjustment to 50 mg /day)

Submission date
24/09/2007

Registration date
26/03/2008

Last Edited
18/04/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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Additional identifiers

EudraCT/CTIS number
2006-005674-47

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Generalized anxiety disorder

Interventions
Agomelatine versus placebo

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Agomelatine

Primary outcome measure
Time to relapse

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

Overall study start date
15/10/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
370

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

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	01/07/2012		Yes	No