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Efficacy and safety of three dose regimens of agomelatine versus placebo given once a day for 6 weeks in out-patients suffering from moderate to severe major depressive disorder

Submission date
09/04/2010

Registration date
18/05/2010

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
2009-011238-84

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CL3-20098-069

Study information

Scientific Title
Efficacy and safety of three dose regimens of agomelatine (10, 25, 25 - 50 mg) versus placebo given once a day for 6 weeks in out-patients suffering from moderate to severe major depressive disorder: a 6-week randomised, double-blind, placebo-controlled, parallel groups study followed by a double-blind optional 18-week extension period

Study objectives
To demonstrate the short term efficacy of at least one of the three dose regimens of agomelatine (versus placebo) using the 17-item Hamilton Rating Scale for Depression (HAM-D-17).

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Ethics Committee approval obtained on 10/06/2009

Study design
Randomised double-blind placebo-controlled parallel group study followed by a double-blind optional extension period

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Major depressive disorder

Interventions
Agomelatine 10, 25 or 50 mg versus placebo for 6 weeks followed by an optional 18-week extension period.

Intervention Type
Drug

Phase
Phase III

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

Primary outcome measure
HAM-D total score, on the week 0 - week 6 period

Secondary outcome measures
1. HAM-D items, from baseline to week 24
2. Clinical Global Impression scale, from baseline to week 6 and 24
3. Sheehan Disability Scale, from baseline to week 6 and 24
4. Hospital Anxiety and Depression Scale, from baseline to week 6
5. Safety from baseline to week 6 and 24

Overall study start date
28/10/2009

Completion date
07/04/2012

Eligibility

Key inclusion criteria
1. Out-patients of both genders aged between 18 (or legal age) and 65 years of age
2. Fulfilling Diagnostic and Statistical Manual, Fourth Edition, Text Revision (DSM-IV-TR) criteria for major depressive disorder (MDD) of moderate or severe intensity

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
520

Key exclusion criteria
1. Women of childbearing potential without effective contraception
2. Other types of depression than MDD
3. Severe or uncontrolled organic diseases, likely to interfere with the conduct of the study

Date of first enrolment

28/10/2009

Date of final enrolment
07/04/2012

Locations

Countries of recruitment
Argentina

Bulgaria

Finland

Russian Federation

Slovakia

Ukraine

Study participating centre
Cerviño 4634, 5o B
Buenos Aires
Argentina
BC1425AHQ

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	01/02/2016		Yes	No