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Efficacy and safety of agomelatine given orally compared to placebo, in addition to a mood stabiliser in bipolar I patients with a current major depressive episode. An eight week randomised, double-blind, controlled, parallel group study followed by a double-blind extension treatment period up to one year

Submission date
31/07/2006

Recruitment status
No longer recruiting

Registration date
24/08/2006

Overall study status
Completed

Last Edited
18/04/2018

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

Contact name
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Additional identifiers

EudraCT/CTIS number
2005-004881-17

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CL3-20098-047

Study information

Scientific Title
Efficacy and safety of agomelatine given orally compared to placebo, in addition to a mood stabiliser in bipolar I patients with a current major depressive episode. An eight week randomised, double-blind, controlled, parallel group study followed by a double-blind extension treatment period up to one year

Study objectives
To assess the efficacy of agomelatine compared to placebo in addition to a mood stabiliser in bipolar I patients with a current major depressive episode.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ramsay Health Ethics Committee, 23/03/2006

Study design
Randomised double-blind placebo-controlled parallel-group 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Major depressive episode

Interventions
Agomelatine versus placebo

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Montgomery-Asberg Depression Rating Scale (MADRS) questionnaire

Secondary outcome measures
Safety of agomelatine in addition to a mood stabiliser

Overall study start date
18/07/2006

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Patients of both genders, over 18 years old
2. Fulfilling The Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) criteria for bipolar I disorder with current major depressive episode
3. Treated with a mood stabiliser

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Hepatic or renal failure
2. Abnormal thyroid function
3. Pregnancy
4. Other psychiatric conditions according to DSM-IV TR

Date of first enrolment
18/07/2006

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
France

Study participating centre
Centre Hospitalier Universitaire de Nantes
Nantes
France
44093

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	01/01/2016		Yes	No