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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

Registration date
24/08/2006

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

Clinical Trials Information System (CTIS)
2005-004881-17

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised double-blind placebo-controlled parallel-group study.

Study type(s)
Treatment

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(s)
Montgomery-Asberg Depression Rating Scale (MADRS) questionnaire

Key secondary outcome(s)

Safety of agomelatine in addition to a mood stabiliser

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

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	01/01/2016		Yes	No
Basic results				No	No