

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	<input type="checkbox"/> Prospectively registered
Registration date 24/08/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/04/2018	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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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Contact details

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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

Study design

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

Primary study design

Interventional

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