

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/05/2010	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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Additional identifiers

Clinical Trials Information System (CTIS)

2009-011238-84

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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	01/02/2016		Yes	No
Basic results				No	No

