

Early effect of agomelatine on general interest in outpatients suffering major depressive disorder

Submission date 24/03/2011	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 04/05/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/04/2018	Condition category Mental and Behavioural Disorders	☐ 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

Protocol serial number

CL3-20098-083

Study information

Scientific Title

Early effect of agomelatine on general interest in outpatients suffering major depressive disorder: a parallel group, randomised, double-blind, multicentre study

Study objectives

To assess the early effect of agomelatine on general interest in outpatients suffering from major depressive disorder

Please note that as of 26/11/2012, the anticipated end date for this trial was updated from 30/09/2012 to 30/03/2013.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval was obtained before recruitment of the first participants

Study design

Parallel group randomised double-blind multicentre study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Depression

Interventions

Therapeutic oral doses of agomelatine and therapeutic oral doses of selective serotonin reuptake inhibitors (SSRI) for 12 weeks, a randomised double-blind period

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Agomelatine

Primary outcome(s)

General interest score obtained from the Visual Analogue Scale (VAS) reflecting the item 13 of the QIDS-SR 16 scale

Key secondary outcome(s)

To provide additional efficacy, safety and tolerability data on agomelatine

Completion date

30/03/2013

Eligibility

Key inclusion criteria

1. Male or female outpatients
2. Aged between 18 and 65 years (inclusive) at the time of selection
3. Fulfilling Diagnostic and Statistical Manual of Mental Disorders 4th edition, Text Revision (DSM-IV-TR) criteria for current major depressive episode (MDE) ≤ 12 months, of moderate to severe intensity
4. Major depressive episode diagnosis documented using the brief structured Mini-International Neuropsychiatric Interview (M.I.N.I.)
5. Quick Inventory of Depressive Symptomatology Self-Report (QIDS-SR16) item 13 (General interest) ≥ 2
6. Hamilton Rating Scale for Depression (HAM-D-17) total score ≥ 22
7. Clinical Global Impression - Severity (CGI-S) (Severity of illness) ≥ 4 (moderately to severely ill)
8. Requiring an antidepressant treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patient fulfilling DSM-IV-TR criteria for a MDE of mild intensity or severe episode with psychotic features, catatonic features or with duration < 4 weeks
2. All types of depression other than MDD, according to DSM-IV-TR criteria
3. Marked suicidal intent and/or known suicidal tendencies for the current episode defined as a score of 4 at the item 3 of the HAM-D-17 and/or in the investigator's opinion based on the patient's medical history, previous suicide attempts, quality of social and familial support
4. Pregnancy, breastfeeding or possibility of becoming pregnant during the study and without an effective contraception
5. Hepatic impairment
6. Severe renal insufficiency

Date of first enrolment

23/05/2011

Date of final enrolment

30/03/2013

Locations**Countries of recruitment**

Romania

Study participating centre

Spitalul Clinic de Neuropsihiatrie Craiova

Craiova

Romania

200317

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?
Basic results				No	No