ISRCTN28327843 https://doi.org/10.1186/ISRCTN28327843

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

Submission date	Recruitment status	[X] Prospectively registered
24/03/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/04/2018	Mental and Behavioural Disorders	

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
Prof Tudor Udristoiu

Contact details
Spitalul Clinic de Neuropsihiatrie Craiova
Clinica 1 Psihiatrie
Aleea Potelu No 24
Craiova
Romania
200317

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 tht 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
To provide additional efficacy, safety and tolerability data on agomelatine

Overall study start date
23/05/2011

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) < = 12months, 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

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, previoussuicide 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)

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