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Initiation of agomelatine after antidepressant treatment in outpatients suffering major depressive disorder

Submission date
16/07/2010

Recruitment status
No longer recruiting

Registration date
10/09/2010

Overall study status
Completed

Last Edited
21/04/2020

Condition category
Mental and Behavioural Disorders

[X] 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)
2010-019556-44

Protocol serial number
CL3-20098-073

Study information

Scientific Title

Initiation of agomelatine after antidepressant treatment by SSRI or SNRI in outpatients suffering Major Depressive Disorder. A 3-week, randomised, double then single-blind, controlled, parallel groups, international, multicentre safety study with a 5-week open extension period.

Study objectives
To compare three different ways to initiate agomelatine after antidepressant treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
Randomised double then single-blind controlled parallel group international multicentre safety study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Major depressive disorder

Interventions
Therapeutic oral doses of agomelatine and therapeutic oral doses of previous antidepressant treatment. Run in period, 3-week randomised period then 5-week extension period.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Agomelatine

Primary outcome(s)
Total number of discontinuation emergent symptoms according to the Discontinuation-Emergent Signs and Symptoms check-list evaluated at week 0, week 1, week 2 and week 3.

Key secondary outcome(s))
1. Adverse events (evaluated at all visits)
2. Haematology and biochemistry parameters (at week 0 and week 3 - and week 8 for liver function only)
3. Vital signs (blood pressure and heart rate)
4. Body weight, body mass index (BMI) (ASSE, week 0, week 3 and week 8)

Completion date

31/01/2012

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years
2. Fulfilling Diagnostic and Statistical Manual of Mental Disorders 4th Edition (DSM-IV-TR) criteria for major depressive episode of moderate or severe intensity
3. Diagnosis documented using the brief structured interview Mini International Neuropsychiatric Interview (MINI)
4. Clinical Global Impression scale
5. Requiring a change in antidepressant treatment due to an insufficient treatment efficacy associated or not with poor acceptability

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
316

Key exclusion criteria
1. "High suicidality" according to MINI 5.0.0.
2. Marked suicidal intent and/or suicidal risk for the current episode, according to the investigator's opinion
3. Hepatic impairment

Date of first enrolment
01/11/2010

Date of final enrolment
31/01/2012

Locations

Countries of recruitment
Belgium

Brazil

France

Germany

Hungary

Italy

Portugal

Spain

Study participating centre
Hôpital Bichat - Claude Bernard
Paris
France
75018

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
Basic results			21/04/2020	No	No