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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/09/2010	**Overall study status** Completed	
Last Edited 21/04/2020	**Condition category** 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

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Additional identifiers

EudraCT/CTIS number
2010-019556-44

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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)

Overall study start date
01/11/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

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)

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
Basic results			21/04/2020	No	No