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Observational cohort study to evaluate the safety of agomelatine in standard medical practice in depressed patients

Submission date
06/04/2010

Recruitment status
No longer recruiting

Registration date
27/08/2010

Overall study status
Completed

Last Edited
28/09/2020

Condition category
Mental and Behavioural Disorders

[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CLE-20098-068

Study information

Scientific Title
Observational cohort study to evaluate the safety of agomelatine in standard medical practice in depressed patients: a prospective, observational (non interventional), international, multicentre cohort study

Study objectives
To evaluate in standard medical practice the safety of agomelatine prescribed to depressed patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Ethics Committee approval obtained on 09/11/2009

Study design
Prospective observational (non-interventional) international multicentre cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Please note that this is a non-interventional study; the objective is to evaluate in standard medical practice the safety of agomelatine prescribed to depressed patients.

Dosage: Agomelatine 25 mg tablets - according to the SmPC, 25 mg once daily taken orally at bedtime (up to 50 mg once daily if no improvement of symptoms after 2 weeks of treatment).

Duration: patients followed during a maximum of 28 weeks.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Safety of agomelatine prescribed to depressed patients, measured each time patients will come and visit his/her physician. Please note that participation of patients in the agomelatine cohort will not trigger additional medical follow-up visits. The participating physician will follow patients through control visits planned as part of normal clinical practice.

Secondary outcome measures
No secondary outcome measures

Overall study start date
13/10/2009

Completion date
12/03/2015

Eligibility

Key inclusion criteria
1. Both genders patients aged at least 18 years or legal age of majority (without upper limit of age)
2. Initiated into agomelatine for their current depressive episode
3. Having signed an informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10,000 (agomelatine cohort)

Total final enrolment
1484

Key exclusion criteria
1. Having to stop an ongoing antidepressant with which they were treated with success for their depression

2. Already treated with another antidepressant that they wish to continue in addition to agomelatine
3. Planning to move during the 26 weeks of the follow-up

Date of first enrolment
22/12/2009

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
France

Germany

Italy

Netherlands

Portugal

Spain

Study participating centre
Centre hospitalier Sainte Anne
Paris
France
75014

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
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2020	03/08/2020	Yes	No
Results article	results	01/01/2021	28/09/2020	Yes	No