

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	<input type="checkbox"/> Prospectively registered
Registration date 27/08/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/09/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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 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