

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

<b>Submission date</b> 06/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/08/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/09/2020	<b>Condition category</b> 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

Prof Frédéric Rouillon

### Contact details

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Paris  
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75014

## 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?
<a href="#">Results article</a>	results	01/11/2020	03/08/2020	Yes	No
<a href="#">Results article</a>	results	01/01/2021	28/09/2020	Yes	No