

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

<b>Submission date</b> 16/07/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/09/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/04/2020	<b>Condition category</b> Mental and Behavioural Disorders	<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 Michel Lejoyeux

### Contact details

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Paris  
France  
75018

## 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?
<a href="#">Basic results</a>				No	No
<a href="#">Basic results</a>			21/04/2020	No	No