

# Evaluation of efficacy and clinical benefit of agomelatine in patients with major depressive disorder compared to serotonin-norepinephrine reuptake inhibitor (SNRI)

<b>Submission date</b> 07/04/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/05/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/04/2020	<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

Mrs Christine Marey

### Contact details

50 rue Carnot  
Suresnes  
France  
92284

## Additional identifiers

### EudraCT/CTIS number

2008-004642-92

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers

CL3-20098-062

# Study information

## Scientific Title

Evaluation of efficacy and clinical benefit of agomelatine (25 to 50 mg/day) over a 6-month treatment period in patients with Major Depressive Disorder. A randomised, double-blind, international multicentre study with parallel groups versus duloxetine (60 mg/day). Twenty-four weeks of treatment.

## Study objectives

Long-term antidepressant efficacy of agomelatine compared to serotonin-norepinephrine reuptake inhibitor (SNRI) over a 6-month period.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval was obtained before recruitment of the first participants

## Study design

Randomised double-blind parallel-group international multicentre active-controlled phase III study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

## Health condition(s) or problem(s) studied

Major depressive disorder

## Interventions

Agomelatine 25 or 50 mg versus SNRI over a 6-month period.

## Intervention Type

Drug

## Phase

Phase III

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

Agomelatine

**Primary outcome measure**

Hamilton Rating Scale for Depression (HAM-D) total score, from baseline to week 24.

**Secondary outcome measures**

1. HAM-D items, from baseline to week 24
2. Clinical Global Impression scale, from baseline to week 24
3. Pittsburgh Sleep Quality Index, from baseline to week 24
4. Leeds Sleep Evaluation Questionnaire, from week 1 to week W2
5. Sheehan Disability Scale, from baseline to week 24
6. Safety from baseline to week 24

**Overall study start date**

29/04/2009

**Completion date**

31/10/2010

## Eligibility

**Key inclusion criteria**

1. Aged between 18 and 65 years, either sex
2. Out-patients fulfilling Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria for major depressive disorder

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

400

**Total final enrolment**

418

**Key exclusion criteria**

Women of childbearing potential without effective contraception

**Date of first enrolment**

29/04/2009

**Date of final enrolment**

31/10/2010

## **Locations**

**Countries of recruitment**

Australia

Brazil

Canada

France

Greece

Hungary

Italy

Portugal

South Africa

Spain

United Kingdom

**Study participating centre**

50 Rue Carnot

Suresnes

France

92284

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