Efficacy of agomelatine given orally on improvement of subjective sleep in patients with major depressive disorder: a randomised, double-blind, flexible-dose international multicentre study with parallel groups versus Selective Serotonin Reuptake Inhibitor (SSRI) twelve week treatment plus double-blind extension for 12 weeks

<b>Submission date</b> 15/05/2007	Recruitment status  No longer recruiting	Prospectively registered		
		☐ Protocol		
Registration date 12/07/2007	Overall study status Completed Condition category	Statistical analysis plan		
		[X] Results		
Last Edited		Individual participant data		
21/04/2020	Mental and Behavioural Disorders			

# 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 Emmanuelle Corruble

#### Contact details

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# Additional identifiers

#### Clinical Trials Information System (CTIS)

2006-006540-54

#### Protocol serial number

CL3-20098-063

# Study information

#### Scientific Title

Efficacy of agomelatine (25 to 50 mg/day) given orally on improvement of subjective sleep in patients with Major Depressive Disorder. A randomised, double-blind, flexible-dose international multicentre study with parallel groups versus escitalopram (10 to 20mg/day). Twelve-week treatment plus double-blind extension for 12 weeks.

#### **Study objectives**

To study the effect of agomelatine on subjective sleep versus Selective Serotonin Reuptake Inhibitor (SSRI).

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

First ethics committee approval in Brazil on 01/03/2007 from Comitê de Etica em Pesquisa do Instituto de Providencia dos Servidores do Estado de Minas Gerais - IPSEMG/ Hospital Governador Israël Pinheiro HGIP; registration number: 245/07; in Belo Horizonte

## Study design

Randomised double-blind parallel-group flexible-dose international multicentre comparative phase III 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 versus therapeutic oral doses of SSRI - twelve week treatment plus double-blind extension for twelve weeks.

# **Intervention Type**

Drug

#### Phase

Phase III

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

Agomelatine, Selective Serotonin Reuptake Inhibitor (SSRI)

#### Primary outcome(s)

Improvement of subjective sleep, measured by sleep score compared to SSRI

#### Key secondary outcome(s))

- 1. Evaluation of depression (Hamilton Depression [HAM-D] scale)
- 2. Evaluation of daytime drowsiness

## Completion date

15/04/2009

# **Eligibility**

#### Key inclusion criteria

- 1. Aged between 18 to 70 years (included)
- 2. Male or female
- 3. Fulfilling Diagnostic and Statistical Manual of mental disorders fourth edition (DSM-IV) criteria for major depressive disorder

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

## Age group

Adult

# Lower age limit

18 years

#### Sex

All

## Total final enrolment

324

#### Key exclusion criteria

- 1. Women of childbearing potential without effective contraception as well as pregnant or breastfeeding women
- 2. All types of depression other than major depressive disorder, all other psychiatric disorders

#### Date of first enrolment

22/05/2007

#### Date of final enrolment

15/04/2009

# Locations

# **Countries of recruitment**United Kingdom Australia

Brazil

Canada

France

**Russian Federation** 

South Africa

Study participating centre CHU de Bicêtre - 78 Le Kremlin Bicentre France 94275

# 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?
Basic results				No	No
Basic results			21/04/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes