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

Submission date 15/05/2007	Recruitment status No longer recruiting	Prospectively registered	
		☐ Protocol	
Registration date 12/07/2007	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited	Condition category	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

EudraCT/CTIS number

2006-006540-54

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CI 3-20098-063

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

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

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 measure

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

Secondary outcome measures

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

Overall study start date

22/05/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

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

Australia

Brazil

Canada

France

Russian Federation

South Africa

United Kingdom

Study participating centre CHU de Bicêtre - 78

Le Kremlin Bicentre France 94275

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?
Basic results				No	No
Basic results			21/04/2020	No	No