ISRCTN55250367 https://doi.org/10.1186/ISRCTN55250367

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 [ ] Statistical analysis plan [X] Results [ ] Individual participant data
Registration date 12/07/2007	**Overall study status** Completed	
Last Edited 21/04/2020	**Condition category** 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
CHU de Bicêtre
78 rue du Général Leclerc
Le Kremlin Bicetre
France
94275

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