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Efficacy of agomelatine given orally on rest /activity circadian rhythms in outpatients with major depressive disorder: a randomised, double-blind international study with parallel groups versus Selective Serotonin Reuptake Inhibitor (SSRI). Six-week treatment plus optional continuation for 18 weeks.

Submission date 04/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/06/2007	**Overall study status** Completed	
Last Edited 18/04/2018	**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

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Additional identifiers

Clinical Trials Information System (CTIS)
2004-004009-10

Protocol serial number
CL3-20098-046

Study information

Scientific Title
Efficacy of agomelatine (25 mg/day with potential adjustment to 50 mg) given orally on rest /activity circadian rhythms in outpatients with Major Depressive Disorder. A randomized, double-blind international study with parallel groups versus sertraline (50 mg/day with potential adjustment to 100 mg). Six-week treatment plus optional continuation for 18 weeks.

Study objectives
To demonstrate that agomelatine improves rest/activity circadian rhythms faster than Selective Serotonin Reuptake Inhibitor (SSRI) in outpatients suffering from major depressive disorder.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First ethics committee approval in France received from the local ethics board (Comités de Consultation pour la Protection des Personnes se prêtant à la Recherche Biomédicale [CCPPRB] Paris-Broussais) on the 15/03/2005 (ref: 2005-006)

Study design
Randomised double-blind parallel-group comparative phase III study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Major depressive disorder

Interventions
Agomelatine versus SSRI

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Agomelatine, Selective Serotonin Reuptake Inhibitor (SSRI)

Primary outcome(s)
Efficacy assessed by actimetry recording

Key secondary outcome(s))
1. Depression
2. Sleep

Completion date
30/09/2007

Eligibility

Key inclusion criteria
1. Male or female
2. Out-patients
3. Aged of 18 to 60 years (inclusive)
4. Fulfilling Diagnostic and Statistical Manual of Mental Disorders - fourth edition (DSM-IV) criteria for major depressive disorder
5. Requiring an antidepressant treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
1. Pregnant or breastfeeding, women of childbearing potential without effective contraception
2. All types of depression other than major depressive disorder
3. Severe or uncontrolled disease

Date of first enrolment
01/04/2005

Date of final enrolment
30/09/2007

Locations

Countries of recruitment

Austria

France

Germany

Italy

Poland

Spain

Study participating centre
Centre Hospitalier Sainte-Anne
Paris cedex 14
France
75674

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?
Results article	results	01/02/2010		Yes	No
Basic results				No	No