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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

Registration date
08/06/2007

Overall study status
Completed

Last Edited
18/04/2018

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Additional identifiers

EudraCT/CTIS number
2004-004009-10

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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 versus SSRI

Intervention Type
Drug

Phase
Phase III

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

Primary outcome measure
Efficacy assessed by actimetry recording

Secondary outcome measures
1. Depression
2. Sleep

Overall study start date
01/04/2005

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants

300

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)

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
Results article	results	01/02/2010		Yes	No