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Effects of agomelatine on sleep electroencephalogram parameters compared to selective serotonin reuptake inhibitors in patients with major depressive disorder: a six-week randomised, double-blind parallel group study versus comparator, followed by a double-blind optional treatment extension period up to six months

Submission date
03/04/2007

Registration date
22/06/2007

Last Edited
18/04/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English Summary
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

EudraCT/CTIS number
2006-004716-48

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CL3-20098-056

Study information

Scientific Title
"Effects of agomelatine (25 to 50 mg/day) on sleep EEG parameters compared to escitalopram in patients with Major Depressive Disorder.
A 6-week randomised, double-blind parallel groups study versus comparator, followed by a double-blind optional treatment extension period up to 6 months."

Study hypothesis
To demonstrate that depressed patients treated with agomelatine present a greater improvement in sleep efficiency than patients treated with Selective Serotonin Reuptake Inhibitors (SSRI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
First approval received from the local ethics committee (Comité de Protection des Personnes Ile de France VIII) on the 18/01/2007 (ref: 070101)

Study design
Six-week randomised double-blind parallel groups study with agomelatine versus SSRI, followed by a double-blind optional treatment extension period up to six months with agomelatine versus SSRI

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

Condition
Major Depressive Disorder

Interventions
Therapeutic doses of agomelatine versus therapeutic doses of SSRI.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Agomelatine, SSRI

Primary outcome measure
Effects of agomelatine on sleep Electroencephalogram (EEG) parameters, corresponding to sleep efficiency index, compared to SSRI in patients with major depressive disorder.

Secondary outcome measures
1. Other sleep parameters
2. Subjective sleep parameters
3. Daytime performance
4. Evaluation of depression with the Hamilton rating scale for Depression (HAM-D) scale
5. Safety measured with adverse events, laboratory parameters, and Electrocardiogram (ECG) parameters

Overall study start date
15/02/2007

Overall study end date
30/09/2008

Eligibility

Participant inclusion criteria
1. Aged between 18 and 60 years
2. Male or female
3. Fulfilling Diagnostic and Statistical Manual of mental disorders fourth edition (DSM-IV-TR) criteria for major depressive disorder

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
130

Participant 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

Recruitment start date
15/02/2007

Recruitment end date
30/09/2008

Locations

Countries of recruitment
Australia

Austria

Brazil

Finland

France

Germany

Spain

Taiwan

United Kingdom

Study participating centre
Hôpital Raymond Poincaré
Garches
France
92380

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	01/09/2011	Yes	No