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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

Recruitment status
No longer recruiting

Registration date
22/06/2007

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

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Additional identifiers

Clinical Trials Information System (CTIS)
2006-004716-48

Protocol serial number
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 objectives
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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
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(s)
Effects of agomelatine on sleep Electroencephalogram (EEG) parameters, corresponding to sleep efficiency index, compared to SSRI in patients with major depressive disorder.

Key secondary outcome(s))
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

Completion date
30/09/2008

Eligibility

Key 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

Date of first enrolment
15/02/2007

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
United Kingdom

Australia

Austria

Brazil

Finland

France

Germany

Spain

Taiwan

Study participating centre
Hôpital Raymond Poincaré
Garches
France
92380

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	01/09/2011		Yes	No
Basic results				No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes