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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

### 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 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

### 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

### 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 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

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
130

### 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
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 |