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# Effect of agomelatine on cerebral activity measured by functional magnetic resonance imaging (MRI) in patients with major depressive disorder in comparison to healthy volunteers

**Submission date**
30/10/2008

**Recruitment status**
No longer recruiting

**Registration date**
26/11/2008

**Overall study status**
Completed

**Last Edited**
20/04/2020

**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

**Clinical Trials Information System (CTIS)**
2007-005564-27

**Protocol serial number**
CL2-20098-067

## Study information

## Scientific Title
Effect of agomelatine on cerebral activity measured by functional magnetic resonance imaging (MRI) in patients with major depressive disorder in comparison to healthy volunteers

## Study objectives
To assess the effect of agomelatine compared to placebo, on cerebral activation measured by functional magnetic resonance imaging (fMRI) in major depressive disorder patients.
Comparison to functional MRI profiles of healthy volunteers.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approval received on the 09/07/2008 by CPP Ile de France VI

## Study design
Randomised double-blind placebo-controlled study

## Primary study design
Interventional

## Study type(s)
Treatment

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

## Interventions
Agomelatine 25 mg versus placebo.

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Agomelatine

## Primary outcome(s)
Functional magnetic resonance imaging.

## Key secondary outcome(s))
1. Functional magnetic resonance imaging
2. Hamilton Rating Scale for Depression (HAM-D), Time point: baseline to week 24
3. Clinical Global Impression (CGI), Time point: baseline to week 24
4. Sleep (Leeds Sleep Evaluation Questionnaire [LSEQ]), Time point: baseline to week 24
5. Safety, Time point: baseline to week 24

## Completion date

29/02/2012

# Eligibility

### Key inclusion criteria
Amended 02/12/2010:
1. Healthy volunteers and patients: between 25 and 53 years, female

initial information at time of registration
1. Healthy volunteers and patients: between 25 and 50 years, female
2. Out-patients fulfilling Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) criteria for major depressive disorder (MDD)

### Participant type(s)
Mixed

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### Total final enrolment
44

### Key exclusion criteria
1. Women of childbearing potential without effective contraception
2. Patients meeting DSM-IV-TR current diagnosis of psychiatric disorder other than MDD

### Date of first enrolment
29/09/2008

### Date of final enrolment
29/02/2012

# Locations

### Countries of recruitment
France

### Study participating centre
**CHU Pitié-Salpêtrière - 47**
Paris
France
75013

# 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? |
|---|---|---|---|---|---|
| Basic results | | | | No | No |
| Basic results | | | 20/04/2020 | No | No |