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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
30/09/2026

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)
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

Primary study design
Interventional

Study design
Randomised double-blind placebo-controlled study

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
Yes

Age group
Adult

Lower age limit
25 Years

Upper age limit
53 Years

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?
Results article		28/11/2015	30/09/2026	Yes	No
Basic results				No	No
Basic results			20/04/2020	No	No