

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	<input type="checkbox"/> Prospectively registered
Registration date 26/11/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/04/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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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Contact details

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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 (fMRI) 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	Participant information sheet			No	No
Basic results			20/04/2020	No	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes