

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

☐ Prospectively registered

☐ Protocol

Registration date

26/11/2008

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

20/04/2020

Condition category

Mental and Behavioural Disorders

☐ 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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France

75013

Additional identifiers

EudraCT/CTIS number

2007-005564-27

IRAS number**ClinicalTrials.gov number****Secondary identifying numbers**

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

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 to request a patient information sheet

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 measure

Functional magnetic resonance imaging.

Secondary outcome measures

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

Overall study start date

29/09/2008

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

Age group

Adult

Sex

Female

Target number of participants

60

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)

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

Results and Publications

Publication and dissemination plan

Publication plan:

Summary results are published in <https://clinicaltrials.servier.com>.

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
Basic results			20/04/2020	No	No