ISRCTN53505070 https://doi.org/10.1186/ISRCTN53505070

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
Prof Philippe Fossati

Contact details
CHU Pitié-Salpêtrière - 47
Bd de LHôpital
Paris
France
75013

Additional identifiers

EudraCT/CTIS number
2007-005564-27

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

Institut de Recherches Internationales Servier (France)

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