

Effects of agomelatine on sleep electroencephalogram parameters compared to selective serotonin reuptake inhibitors in patients with major depressive disorder: a six-week randomised, double-blind parallel group study versus comparator, followed by a double-blind optional treatment extension period up to six months

Submission date

03/04/2007

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

22/06/2007

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

18/04/2018

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

Dr Maria-Antonia Quera-Salva

Contact details

Hôpital Raymond Poincaré

104 boulevard Raymond Poincaré

Garches

France

92380

Additional identifiers

EudraCT/CTIS number

2006-004716-48

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

CL3-20098-056

Study information

Scientific Title

"Effects of agomelatine (25 to 50 mg/day) on sleep EEG parameters compared to escitalopram in patients with Major Depressive Disorder.

A 6-week randomised, double-blind parallel groups study versus comparator, followed by a double-blind optional treatment extension period up to 6 months."

Study objectives

To demonstrate that depressed patients treated with agomelatine present a greater improvement in sleep efficiency than patients treated with Selective Serotonin Reuptake Inhibitors (SSRI).

Ethics approval required

Old ethics approval format

Ethics approval(s)

First approval received from the local ethics committee (Comité de Protection des Personnes Ile de France VIII) on the 18/01/2007 (ref: 070101)

Study design

Six-week randomised double-blind parallel groups study with agomelatine versus SSRI, followed by a double-blind optional treatment extension period up to six months with agomelatine versus SSRI

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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Major Depressive Disorder

Interventions

Therapeutic doses of agomelatine versus therapeutic doses of SSRI.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Agomelatine, SSRI

Primary outcome measure

Effects of agomelatine on sleep Electroencephalogram (EEG) parameters, corresponding to sleep efficiency index, compared to SSRI in patients with major depressive disorder.

Secondary outcome measures

1. Other sleep parameters
2. Subjective sleep parameters
3. Daytime performance
4. Evaluation of depression with the Hamilton rating scale for Depression (HAM-D) scale
5. Safety measured with adverse events, laboratory parameters, and Electrocardiogram (ECG) parameters

Overall study start date

15/02/2007

Completion date

30/09/2008

Eligibility**Key inclusion criteria**

1. Aged between 18 and 60 years
2. Male or female
3. Fulfilling Diagnostic and Statistical Manual of mental disorders fourth edition (DSM-IV-TR) criteria for major depressive disorder

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

130

Key exclusion criteria

1. Women of childbearing potential without effective contraception as well as pregnant or breastfeeding women
2. All types of depression other than major depressive disorder

Date of first enrolment

15/02/2007

Date of final enrolment

30/09/2008

Locations**Countries of recruitment**

Australia

Austria

Brazil

Finland

France

Germany

Spain

Taiwan

United Kingdom

Study participating centre

Hôpital Raymond Poincaré

Garches

France

92380

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

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

For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

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?
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[Basic results](#)

[Results article](#)

results

01/09/2011

No

Yes

No

No