

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	<input type="checkbox"/> Prospectively registered
Registration date 22/06/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/04/2018	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

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Additional identifiers

Clinical Trials Information System (CTIS)

2006-004716-48

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

Australia

Austria

Brazil

Finland

France

Germany

Spain

Taiwan

Study participating centre

Hôpital Raymond Poincaré

Garches

France

92380

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	results	01/09/2011		Yes	No
Basic results				No	No