

Efficacy of agomelatine given orally on rest /activity circadian rhythms in outpatients with major depressive disorder: a randomised, double-blind international study with parallel groups versus Selective Serotonin Reuptake Inhibitor (SSRI). Six-week treatment plus optional continuation for 18 weeks.

Submission date 04/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/06/2007	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

Contact name

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Contact details

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France
75674

Additional identifiers

EudraCT/CTIS number

2004-004009-10

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CL3-20098-046

Study information

Scientific Title

Efficacy of agomelatine (25 mg/day with potential adjustment to 50 mg) given orally on rest /activity circadian rhythms in outpatients with Major Depressive Disorder. A randomized, double-blind international study with parallel groups versus sertraline (50 mg/day with potential adjustment to 100 mg). Six-week treatment plus optional continuation for 18 weeks.

Study objectives

To demonstrate that agomelatine improves rest/activity circadian rhythms faster than Selective Serotonin Reuptake Inhibitor (SSRI) in outpatients suffering from major depressive disorder.

Ethics approval required

Old ethics approval format

Ethics approval(s)

First ethics committee approval in France received from the local ethics board (Comités de Consultation pour la Protection des Personnes se prêtant à la Recherche Biomédicale [CCPPRB] Paris-Broussais) on the 15/03/2005 (ref: 2005-006)

Study design

Randomised double-blind parallel-group comparative phase III study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

Agomelatine versus SSRI

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Agomelatine, Selective Serotonin Reuptake Inhibitor (SSRI)

Primary outcome measure

Efficacy assessed by actimetry recording

Secondary outcome measures

1. Depression
2. Sleep

Overall study start date

01/04/2005

Completion date

30/09/2007

Eligibility

Key inclusion criteria

1. Male or female
2. Out-patients
3. Aged of 18 to 60 years (inclusive)
4. Fulfilling Diagnostic and Statistical Manual of Mental Disorders - fourth edition (DSM-IV) criteria for major depressive disorder
5. Requiring an antidepressant treatment

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Both

Target number of participants

Key exclusion criteria

1. Pregnant or breastfeeding, women of childbearing potential without effective contraception
2. All types of depression other than major depressive disorder
3. Severe or uncontrolled disease

Date of first enrolment

01/04/2005

Date of final enrolment

30/09/2007

Locations**Countries of recruitment**

Austria

France

Germany

Italy

Poland

Spain

Study participating centre

Centre Hospitalier Sainte-Anne

Paris cedex 14

France

75674

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?
Basic results				No	No
Results article	results	01/02/2010		Yes	No