# Initiation of agomelatine after antidepressant treatment in outpatients suffering major depressive disorder

Submission date	Recruitment status	[X] Prospectively registered		
16/07/2010	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
10/09/2010	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
21/04/2020	Mental and Behavioural Disorders			

# 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 Michel Lejoyeux

#### Contact details

Hôpital Bichat - Claude Bernard 46 rue Henri Huchard Paris France 75018

# Additional identifiers

**EudraCT/CTIS number** 2010-019556-44

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

CL3-20098-073

# Study information

#### Scientific Title

Initiation of agomelatine after antidepressant treatment by SSRI or SNRI in outpatients suffering Major Depressive Disorder. A 3-week, randomised, double then single-blind, controlled, parallel groups, international, multicentre safety study with a 5-week open extension period.

#### Study objectives

To compare three different ways to initiate agomelatine after antidepressant treatment.

## Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics approval was obtained before recruitment of the first participants

#### Study design

Randomised double then single-blind controlled parallel group international multicentre safety study

#### Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

# Study type(s)

Treatment

## Participant information sheet

# Health condition(s) or problem(s) studied

Major depressive disorder

#### **Interventions**

Therapeutic oral doses of agomelatine and therapeutic oral doses of previous antidepressant treatment. Run in period, 3-week randomised period then 5-week extension period.

#### **Intervention Type**

Drug

#### Phase

Phase III

# Drug/device/biological/vaccine name(s)

Agomelatine

#### Primary outcome measure

Total number of discontinuation emergent symptoms according to the Discontinuation-Emergent Signs and Symptoms check-list evaluated at week 0, week 1, week 2 and week 3.

#### Secondary outcome measures

- 1. Adverse events (evaluated at all visits)
- 2. Haematology and biochemistry parameters (at week 0 and week 3 and week 8 for liver function only)
- 3. Vital signs (blood pressure and heart rate)
- 4. Body weight, body mass index (BMI) (ASSE, week 0, week 3 and week 8)

#### Overall study start date

01/11/2010

#### Completion date

31/01/2012

# Eligibility

#### Key inclusion criteria

- 1. Aged between 18 and 65 years
- 2. Fulfilling Diagnostic and Statistical Manual of Mental Disorders 4th Edition (DSM-IV-TR) criteria for major depressive episode of moderate or severe intensity
- 3. Diagnosis documented using the brief structured interview Mini International Neuropsychiatric Interview (MINI)
- 4. Clinical Global Impression scale
- 5. Requiring a change in antidepressant treatment due to an insufficient treatment efficacy associated or not with poor acceptability

# Participant type(s)

Patient

# Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

# Target number of participants

300

## Total final enrolment

316

## Key exclusion criteria

- 1. "High suicidality" according to MINI 5.0.0.
- 2. Marked suicidal intent and/or suicidal risk for the current episode, according to the

investigator's opinion 3. Hepatic impairment

Date of first enrolment 01/11/2010

Date of final enrolment 31/01/2012

# Locations

# Countries of recruitment

Belgium

Brazil

France

Germany

Hungary

Italy

Portugal

Spain

Study participating centre

Hôpital Bichat - Claude Bernard

Paris

France 75018

# 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
Basic results			21/04/2020	No	No