

# Early effect of agomelatine on general interest in outpatients suffering major depressive disorder

<b>Submission date</b> 24/03/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/05/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/04/2018	<b>Condition category</b> 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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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CL3-20098-083

# Study information

## Scientific Title

Early effect of agomelatine on general interest in outpatients suffering major depressive disorder: a parallel group, randomised, double-blind, multicentre study

## Study objectives

To assess the early effect of agomelatine on general interest in outpatients suffering from major depressive disorder

Please note tht as of 26/11/2012, the anticipated end date for this trial was updated from 30/09/2012 to 30/03/2013.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval was obtained before recruitment of the first participants

## Study design

Parallel group randomised double-blind multicentre 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

Depression

## Interventions

Therapeutic oral doses of agomelatine and therapeutic oral doses of selective serotonin reuptake inhibitors (SSRI) for 12 weeks, a randomised double-blind period

## Intervention Type

Drug

## Phase

Not Applicable

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

Agomelatine

**Primary outcome measure**

General interest score obtained from the Visual Analogue Scale (VAS) reflecting the item 13 of the QIDS-SR 16 scale

**Secondary outcome measures**

To provide additional efficacy, safety and tolerability data on agomelatine

**Overall study start date**

23/05/2011

**Completion date**

30/03/2013

## **Eligibility**

**Key inclusion criteria**

1. Male or female outpatients
2. Aged between 18 and 65 years (inclusive) at the time of selection
3. Fulfilling Diagnostic and Statistical Manual of Mental Disorders 4th edition, Text Revision (DSM-IV-TR) criteria for current major depressive episode (MDE)  $\leq 12$  months, of moderate to severe intensity
4. Major depressive episode diagnosis documented using the brief structured Mini-International Neuropsychiatric Interview (M.I.N.I.)
5. Quick Inventory of Depressive Symptomatology Self-Report (QIDS-SR16) item 13 (General interest)  $\geq 2$
6. Hamilton Rating Scale for Depression (HAM-D-17) total score  $\geq 22$
7. Clinical Global Impression - Severity (CGI-S) (Severity of illness)  $\geq 4$  (moderately to severely ill)
8. Requiring an antidepressant treatment

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

300

**Key exclusion criteria**

1. Patient fulfilling DSM-IV-TR criteria for a MDE of mild intensity or severe episode with psychotic features, catatonic features or with duration  $< 4$  weeks
2. All types of depression other than MDD, according to DSM-IV-TR criteria

3. Marked suicidal intent and/or known suicidal tendencies for the current episode defined as a score of 4 at the item 3 of the HAM-D-17 and/or in the investigator's opinion based on the patient's medical history, previous suicide attempts, quality of social and familial support
4. Pregnancy, breastfeeding or possibility of becoming pregnant during the study and without an effective contraception
5. Hepatic impairment
6. Severe renal insufficiency

**Date of first enrolment**

23/05/2011

**Date of final enrolment**

30/03/2013

## **Locations**

**Countries of recruitment**

Romania

**Study participating centre**

Spitalul Clinic de Neuropsihiatrie Craiova

Craiova

Romania

200317

## **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