

# Efficacy and safety of agomelatine oral administration (25 to 50 mg/day) in elderly patients suffering from major depressive disorder: an 8-week, randomised, double-blind, flexible-dose, parallel groups, placebo-controlled, international, multicentre study followed by an extension double-blind treatment period of 16 weeks

<b>Submission date</b> 07/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/04/2010	<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

Prof Reinhard Heun

### Contact details

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## Additional identifiers

## Clinical Trials Information System (CTIS)

2009-011795-29

### Protocol serial number

CL3-20098-070

## Study information

### Scientific Title

"Efficacy and safety of agomelatine oral administration (25 to 50 mg/day) in elderly patients suffering from Major Depressive Disorder.

A 8-week, randomised, double-blind, flexible-dose, parallel groups, placebo-controlled, international, multicentre study followed by an extension double-blind treatment period of 16 weeks"

### Study objectives

To demonstrate the efficacy of agomelatine compared to placebo using the 17-item Hamilton Rating Scale for Depression (HAM-D-17), after 8 weeks of treatment in elderly out-patients suffering from major depressive disorder.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

First Ethics Committee approval obtained on 18/08/2009 in Finland

### Study design

Randomised double-blind flexible-dose parallel group placebo-controlled international multicentre study, followed by an extension double-blind treatment period

### Primary study design

Interventional

### Study type(s)

Treatment

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

Major depressive disorder

### Interventions

Agomelatine 25 or 50 mg versus placebo. 8-week treatment followed by an extension double-blind treatment period of 16 weeks.

### Intervention Type

Drug

### Phase

Phase III

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

Agomelatine

**Primary outcome(s)**

HAM-D total score, on the week 0 - 8 period

**Key secondary outcome(s)**

1. Clinical Global Impression scale scores, from baseline to week 8 and 24
2. Sheehan Disability Scale scores, from baseline to week 8 and 24
3. Safety from baseline to week 8 and 24

**Completion date**

31/10/2011

## **Eligibility**

**Key inclusion criteria**

1. Out-patients of both genders aged more than 65 years
2. Fulfilling Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision (DSM-IV-TR) criteria for a moderate to severe episode of a recurrent major depressive disorder

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Key exclusion criteria**

1. All types of depression other than major depressive disorder recurrent
2. Severe or uncontrolled organic diseases, likely to interfere with the conduct of the study
3. Current diagnosis of neurological disorders

**Date of first enrolment**

04/11/2009

**Date of final enrolment**

31/10/2011

## **Locations**

**Countries of recruitment**

United Kingdom

England

Argentina

Finland

Mexico

Portugal

Romania

### **Study participating centre**

**Radbourne Unit**

Derby

United Kingdom

DE22 3NE

## **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?
<a href="#">Results article</a>	results	01/06/2013		Yes	No
<a href="#">Results article</a>	results	01/07/2017		Yes	No
<a href="#">Basic results</a>				No	No