

# Efficacy of agomelatine given orally on the quality of remission in elderly depressed patients, after a 12-week treatment period. A randomised, double-blind, flexible-dose international multicentre study with parallel groups versus SSRI drug. Twelve-week treatment plus optional continuation for 12 weeks.

<b>Submission date</b> 24/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 31/03/2006	<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

## Clinical Trials Information System (CTIS)

2005-002388-95

## Protocol serial number

CL3-20098-048

# Study information

## Scientific Title

Efficacy of agomelatine (25 to 50 mg/day) given orally on quality of remission in elderly depressed patients, after a 12-week treatment period. A randomised, double-blind, flexible-dose international multicentre study with parallel groups versus paroxetine (20 to 30 mg/day). Twelve-week treatment plus optional continuation for 12 weeks.

## Study objectives

To show the efficacy of agomelatine in improving the quality of remission in elderly depressed patients.

On 26/11/2012 the anticipated end date of this trial was updated from 30/10/2007 to 30/04/2008.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

First approved by the Ethical Committee of Clinical Investigations, Clinical Hospital of San Carlos (Comite Etico de Investigacion Clinica, Hospital Clinico, San Carlos) on 05/08/2005 in Spain, reference number: 05/165-R

## Study design

Randomised double-blind flexible-dose international multicentre study with parallel groups versus SSRI drug

## Primary study design

Interventional

## Study type(s)

Treatment

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

Major depressive disorder

## Interventions

Agomelatine versus SSRI drug

## Intervention Type

Drug

**Phase**

Not Applicable

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

Agomelatine

**Primary outcome(s)**

Quality of sleep

**Key secondary outcome(s)**

1. Other sleep patterns
2. Quality of life
3. Daytime drowsiness
4. Residual symptoms of depression

**Completion date**

30/04/2008

**Eligibility****Key inclusion criteria**

Out-patients aged at least 60 years with recurrent major depressive episode according to diagnostic and statistical manual of mental disorders (DSM) IV

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Patients treated with electroconvulsive therapy (ECT) within the last three months
2. Insight-oriented and structured psychotherapy started within the three months before inclusion
3. Light-therapy started within two weeks before inclusion
4. Current diagnosis of neurological disorders
5. Cognitive dysfunction
6. Severe or uncontrolled organic disease, likely to interfere with the conduct of the study

**Date of first enrolment**

07/10/2005

**Date of final enrolment**

30/04/2008

# Locations

## Countries of recruitment

Austria

Belgium

Denmark

France

Hungary

Italy

Norway

Poland

Portugal

Spain

## Study participating centre

**CHU de Grenoble-Hopital Sud**

Grenoble

France

38042

# 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	01/01/2013		Yes	No
<a href="#">Basic results</a>				No	No