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# 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.

**Submission date**
24/01/2006

**Registration date**
31/03/2006

**Last Edited**
18/04/2018

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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# Additional identifiers

### EudraCT/CTIS number
2005-002388-95

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### 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 drug

### Intervention Type
Drug

### Phase
Not Applicable

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

### Primary outcome measure
Quality of sleep

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

### Overall study start date
07/10/2005

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
400

### 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)

### 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 | 01/01/2013 | | Yes | No |