ISRCTN68222771 https://doi.org/10.1186/ISRCTN68222771

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