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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

Submission date
07/04/2010

Registration date
30/04/2010

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
2009-011795-29

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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

Secondary outcome measures
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

Overall study start date
04/11/2009

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

Age group
Senior

Sex
Both

Target number of participants
210

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
Argentina

England

Finland

Mexico

Portugal

Romania

United Kingdom

Study participating centre
Radbourne Unit
Derby
United Kingdom
DE22 3NE

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	01/06/2013		Yes	No
Results article	results	01/07/2017		Yes	No