

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

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

30/04/2010

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

18/04/2018

Condition category

Mental and Behavioural Disorders

☐ 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

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

Radbourn 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