

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	<input type="checkbox"/> Prospectively registered
Registration date 30/04/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/04/2018	Condition category 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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Additional identifiers

Clinical Trials Information System (CTIS)

2009-011795-29

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised double-blind flexible-dose parallel group placebo-controlled international multicentre study, followed by an extension double-blind treatment period

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

United Kingdom

England

Argentina

Finland

Mexico

Portugal

Romania

Study participating centre

Radbourne Unit

Derby

United Kingdom

DE22 3NE

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