

Efficacy and safety of agomelatine (25 mg/day with potential adjustment to 50 mg) given orally for eight weeks in out-patients with severe major depressive disorder: a randomised double-blind, parallel groups, international study versus selective serotonin reuptake inhibitor (SSRI) with a double-blind extension period of 16 weeks

Submission date

29/07/2008

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

19/08/2008

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

28/03/2018

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 Anthony Hale

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2004-004008-19

Protocol serial number

CL3-20098-045

Study information

Scientific Title

Efficacy and safety of agomelatine (25 mg/day with potential adjustment to 50 mg) given orally for 8 weeks in out-patients with severe Major Depressive Disorder. A randomised double-blind, parallel groups, international study versus fluoxetine (20 mg/day with potential adjustment to 40 mg) with a double-blind extension period of 16 weeks.

Study objectives

To assess the agomelatine superiority to selective serotonin reuptake inhibitor (SSRI) after an eight-week treatment in out-patients suffering from severe major depressive disorder.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval was obtained before recruitment of the first participants

Primary study design

Interventional

Study design

Randomised, double-blind, parallel-group, comparative phase III study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Major depressive disorder

Interventions

1. Agomelatine: 25 mg/day with potential adjustment to 50 mg, given orally for eight weeks
2. Selective serotonin reuptake inhibitor (SSRI)

Followed by an extension double-blind period for 16 weeks.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Agomelatine, selective serotonin reuptake inhibitor (SSRI)

Primary outcome(s)

Hamilton Depression Rating Scale (HAM-D) total score will be assessed from baseline to week 24.

Key secondary outcome(s)

1. Clinical Global Impressions (CGI) Scale
2. Leeds Sleep Evaluation Questionnaire (LSEQ)
3. Hamilton Rating Scale for Anxiety (HAM-A)
4. Safety

Assessed from baseline to week 24.

Completion date

14/03/2008

Eligibility**Key inclusion criteria**

1. Aged 18 to 65 years
2. Male or female
3. Out-patients
4. Fulfilling Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) criteria for major depressive disorder

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Pregnancy, breastfeeding or possibility of becoming pregnant during the study
2. All types of depression other than major depressive disorder
3. Severe or uncontrolled organic disease

Date of first enrolment

06/10/2005

Date of final enrolment

14/03/2008

Locations

Countries of recruitment

United Kingdom

England

Argentina

Brazil

Italy

Spain

Study participating centre

Eastern and Costal Headquarters

Kent

United Kingdom

CT1 1AZ

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	01/11/2010		Yes	No
Basic results				No	No