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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 [ ] Statistical analysis plan [X] Results [ ] Individual participant data
Registration date 19/08/2008	**Overall study status** Completed	
Last Edited 28/03/2018	**Condition category** Mental and Behavioural Disorders	

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
2004-004008-19

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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

Secondary outcome measures
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.

Overall study start date
06/10/2005

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

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
500

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
Argentina

Brazil

England

Italy

Spain

United Kingdom

Study participating centre
Eastern and Costal Headquarters
Kent
United Kingdom
CT1 1AZ

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 on 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	01/11/2010		Yes	No