ISRCTN96725312 https://doi.org/10.1186/ISRCTN96725312

Evaluation of efficacy and clinical benefit of agomelatine in patients with major depressive disorder compared to serotonin-norepinephrine reuptake inhibitor (SNRI)

Submission date 07/04/2009	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [X] Results [ ] Individual participant data
Registration date 08/05/2009	**Overall study status** Completed	
Last Edited 21/04/2020	**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

Contact name
Mrs Christine Marey

Contact details
50 rue Carnot
Suresnes
France
92284

Additional identifiers

EudraCT/CTIS number
2008-004642-92

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CL3-20098-062

Study information

Scientific Title
Evaluation of efficacy and clinical benefit of agomelatine (25 to 50 mg/day) over a 6-month treatment period in patients with Major Depressive Disorder.A randomised, double-blind, international multicentre study with parallel groups versus duloxetine (60 mg/day).Twenty-four weeks of treatment.

Study objectives
Long-term antidepressant efficacy of agomelatine compared to serotonin-norepinephrine reuptake inhibitor (SNRI) over a 6-month period.

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 international multicentre active-controlled 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
Agomelatine 25 or 50 mg versus SNRI over a 6-month period.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Agomelatine

Primary outcome measure
Hamilton Rating Scale for Depression (HAM-D) total score, from baseline to week 24.

Secondary outcome measures
1. HAM-D items, from baseline to week 24
2. Clinical Global Impression scale, from baseline to week 24
3. Pittsburgh Sleep Quality Index, from baseline to week 24
4. Leeds Sleep Evaluation Questionnaire, from week 1 to week W2
5. Sheehan Disability Scale, from baseline to week 24
6. Safety from baseline to week 24

Overall study start date
29/04/2009

Completion date
31/10/2010

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years, either sex
2. Out-patients fulfilling Diagnostic and Statistical Manual of Mental Disorders, 4th 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
400

Total final enrolment
418

Key exclusion criteria
Women of childbearing potential without effective contraception

Date of first enrolment
29/04/2009

Date of final enrolment
31/10/2010

Locations

Countries of recruitment
Australia

Brazil

Canada

France

Greece

Hungary

Italy

Portugal

South Africa

Spain

United Kingdom

Study participating centre
50 Rue Carnot
Suresnes
France
92284

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
Basic results			21/04/2020	No	No