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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

Registration date
08/05/2009

Overall study status
Completed

Last Edited
21/04/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-004642-92

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

Australia

Brazil

Canada

France

Greece

Hungary

Italy

Portugal

South Africa

Spain

Study participating centre
50 Rue Carnot
Suresnes
France
92284

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?
Basic results				No	No
Basic results			21/04/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes