ISRCTN53193024 https://doi.org/10.1186/ISRCTN53193024

A study to determine the maintenance of efficacy of agomelatine to prevent relapse in out-patients with major depressive disorder. A 8 to 10 weeks open period treatment with agomelatine followed by 24 weeks randomised double-blind period, placebo-controlled, parallel groups and 20 weeks of optional double-blind treatment period.

Submission date
06/02/2007

Recruitment status
No longer recruiting

Registration date
16/03/2007

Overall study status
Completed

Last Edited
28/03/2018

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

EudraCT/CTIS number
2004-003981-13

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CL3-20098-041

Study information

Scientific Title
A study to determine the maintenance of efficacy of agomelatine (25 mg to 50 mg) to prevent relapse in out-patients with Major Depressive Disorder. A 8 to 10 weeks open period treatment with agomelatine (25 mg to 50 mg) followed by 24 weeks randomised double-blind period, placebo-controlled, parallel groups and 20 weeks of optional double-blind treatment period.

Study objectives
To assess the efficacy of agomelatine in the prevention of depressive relapse, in ambulatory patients suffering from major depressive disorder

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sub-Committee on Medical Research Ethics (TUJIKA) of the National Advisory Board on Health Care Ethics, Finland, 01/11/2004

Study design
Randomised double-blind parallel group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
A 8- to 10-week open treatment period with agomelatine followed by 24-week randomised double-blind period, placebo-controlled, parallel groups and 20 weeks of optional double-blind treatment period

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Efficacy in the prevention of depressive relapse, measured by Hamilton Depression Rating Scale (HAMD) - questionnaire

Secondary outcome measures
Safety parameters, meausred by Adverse Event reporting

Overall study start date
09/02/2005

Completion date
30/06/2007

Eligibility

Key inclusion criteria
1. Aged 18 to 65 years
2. Male or female
3. Out-patients
4. Requiring an antidepressant treatment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
1. All types of depression other than major depressive disorder
2. Severe or uncontrolled organic disease
3. Pregnant or breastfeeding women

Date of first enrolment
09/02/2005

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
Australia

Finland

France

South Africa

United Kingdom

Study participating centre
Hôpital Albert Chenevier - 40 rue de Mesly
Créteil
France
94000

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	01/08/2009		Yes	No
Results article	results	01/01/2013		Yes	No