

# 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

☐ Prospectively registered

☐ Protocol

**Registration date**

16/03/2007

**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 Frederic Rouillon

**Contact details**

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Créteil

France

94000

## 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 (TUJIKÄ) 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, measured 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?
<a href="#">Basic results</a>				No	No
<a href="#">Results article</a>	results	01/08/2009		Yes	No
<a href="#">Results article</a>	results	01/01/2013		Yes	No