# Clinical efficacy of Valdoxan® in everyday practice conditions (efficiency)

Submission date	Recruitment status	Prospectively registered		
26/05/2009	No longer recruiting	☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
15/07/2009		[X] Results		
Last Edited	Condition category	Individual participant data		
21/04/2020	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

Prof Pierre-Michel Llorca

#### Contact details

CHU Hôpital Gabriel Montpied 58 rue Montalembert Clermont-Ferrand France 63003

# Additional identifiers

# EudraCT/CTIS number

2008-008220-32

**IRAS** number

ClinicalTrials.gov number

# Secondary identifying numbers

DM4-20098-108

# Study information

#### Scientific Title

Clinical efficacy of VALDOXAN in everyday practice conditions (efficiency) in depressed patients, on a treatment-naive or switch basis. Phase-IV, multicentre, open, interventional clinical study. VALDOXAN D-CHANGE Study

#### Acronym

Etude Valdoxan® D-Change

#### **Study objectives**

Clinical efficiency of Valdoxan® after 6 weeks of treatment.

Please note that as of 26/11/2012 the anticipated end date for this study has been updated from 30/04/2010 to 30/06/2010.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics approval was obtained before recruitment of the first participants

#### Study design

Phase IV multicentre open interventional clinical study

#### Primary study design

Interventional

## Secondary study design

Randomised controlled trial

#### Study setting(s)

Other

# Study type(s)

Treatment

# Participant information sheet

# Health condition(s) or problem(s) studied

Major depressive episode

#### Interventions

Agomelatine 25 or 50 mg over a 6-week period.

# Intervention Type

Drug

#### Phase

Phase IV

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

#### Primary outcome measure

Assessment of the response to the treatment based on Clinical Global Impression Improvement (CGI-I) Scale, Patient Global Impression Improvement (PGI-I) Scale, Leeds Sleep Evaluation Questionnaire (LSEQ) and patients wish to continue the study treatment at week 6.

#### Secondary outcome measures

- 1. Sheehan Disability Scale (SDS) from baseline to week 6
- 2. MAThyS from baseline to week 6
- 3. CGI-EI from week 2 to week 6
- 4. Safety from baseline to week 6

#### Overall study start date

20/04/2009

#### Completion date

30/06/2010

# Eligibility

#### Key inclusion criteria

- 1. Patients older than 18 years (inclusive), 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

4,000

#### Total final enrolment

2938

#### Key exclusion criteria

Women of childbearing potential without effective contraception

#### Date of first enrolment

20/04/2009

#### Date of final enrolment

30/06/2010

# Locations

#### Countries of recruitment

France

# Study participating centre CHU Hôpital Gabriel Montpied

CHU Höpital Gabriel Montpi 58 rue Montalembert Clermont-Ferrand France 63003

# 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