ISRCTN68100949 https://doi.org/10.1186/ISRCTN68100949

# 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** | [ ] Statistical analysis plan |
| 15/07/2009 | Completed | [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**
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## 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)

Valdoxan®

### 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**
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 |