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

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-008220-32

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

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