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VITAL Germany (Valdoxan® Improves Treatment of depression and daytime Activity in real Life)

Submission date	Recruitment status	[_] Prospectively registered
13/01/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/03/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/09/2019	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IC4-20098-93-DEU

Study information

Scientific Title
VITAL Germany (Valdoxan® improves treatment of depression and daytime activity in real life) : an observational prospective multicentre study

Acronym
VITAL Germany

Study objectives
Effects of Valdoxan® therapy on depressive symptoms, daytime well-being and compliance in adult patients with episodes of major depression under daily routine in an observational prospective multicentre trial by psychiatrists and general practitioners.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Freiburger Ethics Committee International approved on 25/10/2010 (ref: 010/2141)

Study design
Observational prospective multicentre study

Primary study design
Observational

Secondary study design
Multi-centre

Study setting(s)
Other

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
Episodes of major depression

Interventions
1. Get information on Valdoxan® therapy under daily routine practice by psychiatrists and general practitioners:
1.1. Changes in depressive symptoms under daily routine conditions via CGI (Clinical Global Impressions)
1.2. Effects of the therapy on depressive symptoms and daytime well-being via patients-questionnaire Beck Depression Inventory (BDI-II) and Circ-Screen questions 5 and 6
1.3. Compliance via standardised questions to the patients

2. Get information about how Valdoxan® SmPC and patients information are followed via standardised documentation of the dosage of Valdoxan®, of comedications and concomittant diseases
3. Analysis of the general tolerability of Valdoxan® under routine conditions via standardised adverse drug reactions' documentation and standardised documentation of therapy discontinuation
4. Analysis of unknown adverse drug reactions via standardised documentation
5. Get further information on known adverse drug reactions under routine practice via standardised adverse drug reactions' documentation and laboratory parameter (liver function testing)

Study duration is about 6 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Valdoxan®

Primary outcome measure
1. Get informations on Valdoxan® therapy under daily routine practice by psychiatrists and general practitioners:
1.1. Changes in depressive symptoms under daily routine conditions via CGI (Clinical Global Impressions): measured at U0 (inclusion), U2 (after 2 weeks), U3 (after 6 weeks), U4 (after 12 weeks) and U5 (after 24 weeks)
1.2. Effects of the therapy on depressive symptoms and daytime well-being via patient-questionnaire Beck Depression Inventory (BDI-II) and Circ-Screen questions 5 and 6: measured at U0 (inclusion), U2 (after 2 weeks), U4 (after 12 weeks) and U5 (after 24 weeks)
1.3. Compliance via standardised questions to the patients: measured at U0 (inclusion), U2 (after 2 weeks), U4 (after 12 weeks) and U5 (after 24 weeks)
2. Get information about how Valdoxan® SmPC and patients information are followed via standardised documentation of the dosage of Valdoxan® and of comedications (measured at U0 [inclusion], U2 [after 2 weeks], U3 [after 6 weeks], U4 [after 12 weeks] and U5 [after 24 weeks]) and concomitant diseases (measured at U0 [inclusion])
3. Analysis of the general tolerability of Valdoxan® under routine conditions via standardised adverse drug reactions' documentation and standardised documentation of therapy discontinuation: measured at U2 (after 2 weeks), U3 (after 6 weeks), U4 (after 12 weeks) and U5 (after 24 weeks)
4. Analysis of unknown adverse drug reactions via standardised documentation: measured at U2 (after 2 weeks), U3 (after 6 weeks), U4 (after 12 weeks) and U5 (after 24 weeks)
5. Get further information on known adverse drug reactions under routine practice via standardised adverse drug reactions´documentation and laboratory parameter (liver function testing): measured at U2 (after 2 weeks), U3 (after 6 weeks), U4 (after 12 weeks) and U5 (after 24 weeks)

Secondary outcome measures
No secondary outcome measures

Overall study start date
13/01/2011

Completion date
31/03/2012

Eligibility

Key inclusion criteria
Adult patients with episodes of major depression

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
4200 patients

Total final enrolment
3005

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
13/01/2011

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
Germany

Study participating centre
Elsenheimer Str. 53
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Sponsor information

Organisation
Servier Deutschland GmbH (Germany)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Servier Deutschland GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/08/2016	13/09/2019	Yes	No