

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

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| Submission date 13/01/2011 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 25/03/2011 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 13/09/2019 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> 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

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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

Munich

Germany

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Sponsor information

Organisation

Servier Deutschland GmbH (Germany)

Sponsor details

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Sponsor type

Industry

Website

<http://www.servier.com/>

ROR

<https://ror.org/05wk4ae67>

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 |