

Valdoxan Improves depression with anxiety symptoms (VIVRE)

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| Submission date 10/05/2012 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 19/06/2012 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 11/09/2019 | 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

Background and study aims

Depression is currently one of the most frequent psychiatric diseases. Patients with depression suffer very much of depressed mood, loss of interest or pleasure in activity, and they are often impaired emotionally and socially in their daily functioning. Depressed patients also often complain about symptoms of anxiety in combination with their symptoms of depression. The aim of this study is to observe the effects of Valdoxan® , a drug that acts as an antidepressant and specifically resynchronizes circadian rhythms, such as diurnal variation of the mood, disrupted daily rhythms and impaired daytime alertness, as well as disturbed sleep/wake-rhythms. Besides that, the effect on social and emotional functioning is observed, and the effect on anxiety symptoms in combination with depression. We also intend to assess how safe and tolerated this drug is.

Who can participate?

Ambulatory (who can walk) adult patients (no age and gender limitation) with major depression, who have been prescribed Valdoxan® before entering the study.

What does the study involve?

All patients observed in this study will be treated with Valdoxan®. The doctor will keep a record of the baseline status of the patient, including other diseases and other medications. The doctor will document the patient and control the symptoms of depression within the further course of treatment. The follow-up visits, according to his clinical routine, will take place after about three weeks, after about six weeks and a last control after about 12 weeks. During these visits a routine practice investigation will be carried out and the doctor will ask about the symptoms of depression and complete a case report form regarding the severity of depression. The patients will be asked to fill out the brief patients' questionnaire for orientation concerning the severity of depressive symptoms (adapted CGI) and social and emotional impairment (Sheehan disability scale) at each visit. According to the antidepressant effect, the dosage of Valdoxan® can be adapted at first follow-up visit (after about week 3) or afterwards in the course of treatment. The duration of the observation of the patients will be three months.

What are the possible benefits and risks of participating?

There are no particular benefits or risks. The treatment that the patient receives corresponds to

the daily routine of the doctor. The doctor prescribes the drug according to the patients' diagnosis and the indication of the drug. Patients are free to withdraw from the study at any time without giving a particular reason and without any consequences on further treatment.

Where is the study run from?

The study will take place all over Germany. It is planned that the study will be carried out by approximately 1000 doctors, mainly psychiatrists (practice-based or in outpatient clinics).

When is the study starting and how long is it expected to run for?

From 23 April 2012 until 31 January 2013. The recruitment of participants runs until 31 July 2012.

Who is funding the study?

Servier Deutschland, GmbH.

Who is the main contact?

Dr Bettina Barthel

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

IC4-20098-128-DEU

Study information

Scientific Title

Valdoxan ImproVes depRession with anxiEty symptoms: a non-interventional study

Acronym

VIVRE

Study objectives

Effects of Valdoxan therapy on depressive symptoms, emotional and social functioning and anxiety symptoms within depression in adult patients with episodes of major depression under daily routine in an observational, non-interventional prospective multicentre trial by psychiatrists.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Freiburger International Ethics Committee, 13/02/2012, ref: 012/1098

Study design

Observational non-interventional prospective multicentre study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Episodes of major depression

Interventions

Observational period: 3 months, where the following will be documented:

1. Course of depressive symptoms (CGI, adapted version of CGI for patients)
2. Evolution of social and emotional functioning (SDS)
3. Evolution of anxiety symptoms within depression (COVI)
4. Adverse drug reactions
5. Liver function tests, if tested

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Valdoxan

Primary outcome(s)

Obtain information on Valdoxan therapy under daily routine practice by psychiatrists:

1. Changes in depressive symptoms under daily conditions via CGI (Clinical Global impression) and anxiety symptoms within depression via COVI-scale
2. Effects of the treatment on depressive symptoms via patients' questionnaire (adapted CGI) and emotional and social functioning via SDS (Sheehan disability scale)
3. Get information about how Valdoxan SmPC and patients information are followed via standardized documentation of the dosage of Valdoxan, of comedication and concomitant diseases
4. Analysis of the general tolerability of Valdoxan under routine conditions via standardized adverse drug reactions' documentation and standardized documentation of therapy

discontinuation

5. Analysis of unknown adverse drug reactions via standardized documentation

6. Get further information on known adverse drug reactions under routine practice in comorbide and comedicated patients via standardized adverse drug reactions' documentation and laboratory parameters (liver function testing)

Key secondary outcome(s))

No secondary outcome measures

Completion date

31/01/2013

Eligibility

Key inclusion criteria

Adult patients with episodes of major depression according to the SmPC

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

23/04/2012

Date of final enrolment

31/07/2012

Locations

Countries of recruitment

Germany

Study participating centre

Servier Deutschland GmbH

Munich

Germany

80687

Sponsor information

Organisation

Servier Deutschland GmbH (Germany)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Servier Deutschland GmbH (Germany)

Results and Publications

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 | | 18/01/2019 | Yes | No |
| Results article | results | | 18/01/2019 | Yes | No |