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Valdoxan ImproVes depRession with anxiEty symptoms (VIVRE)

Submission date
10/05/2012

Recruitment status
No longer recruiting

Registration date
19/06/2012

Overall study status
Completed

Last Edited
11/09/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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, nin-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

Secondary study design
Cohort study

Study setting(s)
Hospital

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
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 measure
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 comedicatins and concomittant 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)

Secondary outcome measures
No secondary outcome measures

Overall study start date
23/04/2012

Completion date
31/01/2013

Eligibility

Key inclusion criteria
Adult patients with episodes of major depression according to the SmPC

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3000 patients

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)

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Sponsor type
Industry

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