

VIVALDI: Valdoxan® improves depressive symptoms and normalises circadian rhythms

Submission date 26/02/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/05/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/01/2019	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

Protocol serial number

IC4-20098-63-DEU

Study information

Scientific Title

VIVALDI: Valdoxan® improves depressive symptoms and normalises circadian rhythms - an observational prospective study

Acronym

VIVALDI

Study objectives

Effects of Valdoxan® therapy on depressive symptoms and circadian rhythm dysfunction in adult patients with episodes of major depression under daily routine in an observational prospective multi-centre trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Freiburger Ethics Commission International (feci), approved on 19/12/2008 (ref: 08/2694)

Study design

Observational prospective longitudinal multi-centre study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Episodes of major depression

Interventions

1. Get informations on Valdoxan® (oral) therapy under daily routine practice:
 - 1.1. Changes in depressive symptoms under daily routine conditions via a short version of the Montgomery-Asberg Depression Rating Scale (MADRS) and Clinical Global Impressions (CGI) questionnaire
 - 1.2. Effects of the therapy on circadian rhythm dysfunction and sleep via CircScreen patients questionnaire
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 standardized documentation of therapy discontinuation
4. Analysis of unknown adverse drug reactions via standardized documentation
5. Get further information on known adverse drug reactions under routine practice via standardized adverse drug reaction documentation and laboratory parameter (liver function testing)

Study duration: 3 months. Optional follow-up period of 9 months.

There will be 4 assessment-visits in VIVALDI (duration approx. 3 months) and a total of 6 assessment visits for patients included in VIVALDI follow-up (further 9 months). Study duration = approx. 12 months for patients included in the follow-up.

Visit 1 = inclusion visit

Visit 2 = control visit (approx. 2 weeks after inclusion visit)

Visit 3 = control visit (approx. 6 weeks after inclusion visit)

Visit 4 = final visit (approx. 12 weeks after inclusion visit for patients who are not included in the follow-up)

VIVALDI Follow-up (further 9 months):

Visit 5 = first control visit of the follow-up (approx. 6 months after inclusion visit)

Visit 6 = final visit of the follow-up (approx. 12 months after inclusion visit)

All primary outcome measures will be assessed at inclusion visit, visit 2, visit 3, visit 4, visit 5, visit 6.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Agomelatine (Valdoxan®)

Primary outcome(s)

1. Get information on Valdoxan® therapy under daily routine practice:

1.1. Changes in depressive symptoms under daily routine conditions via a short version of the Montgomery-Asberg Depression Rating Scale (MADRS) and Clinical Global Impressions (CGI) questionnaire

1.2. Effects of the therapy on circadian rhythm dysfunction and sleep via CircScreen patients questionnaire

2. Get information about how Valdoxan SmPC and patients information are followed via standardised documentation of the dosage of Valdoxan®, of comedications and concomitant 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 reaction documentation and laboratory parameter (liver function testing)

All primary outcome measures will be assessed at inclusion visit, visit 2, visit 3, visit 4, visit 5, visit 6.

Key secondary outcome(s)

No secondary outcome measures

Completion date

30/10/2010

Eligibility

Key inclusion criteria

1. Both males and females, adult patients (≥ 18 years)
2. Episodes of major depression

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

16/03/2009

Date of final enrolment

30/10/2010

Locations**Countries of recruitment**

Germany

Study participating centre

Elsenheimer str. 53

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	01/11/2012	18/01/2019	Yes	No