

# VIVALDI Praxis: Valdoxan improves depressive symptoms and normalizes circadian rhythms

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| <b>Submission date</b><br>11/03/2010   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>22/04/2010 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>07/01/2021       | <b>Condition category</b><br>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

### Contact name

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## Additional identifiers

### Protocol serial number

IC4-20098-92-DEU

## Study information

### Scientific Title

VIVALDI Praxis: Valdoxan improves depressive symptoms and normalizes circadian rhythms: A prospective multicentre observational study

### Acronym

VIVALDI Praxis

### **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 multicentre trial by general practitioners and internists

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Freiburger Ethics Committee International (Mozartstr. 21, 79104 Freiburg [Germany] - Prof. Hans-Peter Graf, MD, PhD) approved on 26/10/2009 (feki code: 09/2435)

### **Primary study design**

Observational

### **Study design**

Observational prospective multicentre study

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Episodes of major depression

### **Interventions**

Data on Valdoxan therapy for the treatment of major depression in daily routine practice will be collected from general practitioners, internists and their patients over a 3 month period.

### **Intervention Type**

Other

### **Phase**

Phase IV

### **Primary outcome(s)**

1. Get information on Valdoxan therapy under daily routine practice by general practitioners and internists:

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

1.2. Effects of the therapy on quality of life and satisfaction of patients via patients-questionnaire (Q-LES-Q-SF)

1.3. Effects of the therapy on circadian rhythms via patients-questionnaire (questions 1, 2 and 5 of CircScreen)

2. Get information about how Valdoxan SmPC and patients' information are followed via standardized 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 standardized adverse drug reactions documentation and laboratory parameter (liver function testing)

Outcomes will be measured at baseline, after approx. 2 weeks, after approx. 6 weeks and after approx. 12 weeks.

**Key secondary outcome(s)**

No secondary outcome measures

**Completion date**

30/09/2010

## **Eligibility**

**Key inclusion criteria**

Adult patients with episodes of major depression

**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**

13/01/2010

**Date of final enrolment**

30/09/2010

## **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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 03/06/2015   | 07/01/2021 | Yes            | No              |
| <a href="#">Results article</a> | results | 01/04/2017   | 07/01/2021 | Yes            | No              |