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VIVALDI Praxis: Valdoxan improves depressive symptoms and normalizes circadian rhythms

Submission date	Recruitment status	[ ] Prospectively registered
11/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/01/2021	Mental and Behavioural Disorders	

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
Dr Martin Kühn

Contact details
Elsenheimer Str. 53
Munich
Germany
80687
+49 (0)89 57095308
martin.kuehn@de.netgrs.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Observational prospective multicentre study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
GP practice

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
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 measure
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.

Secondary outcome measures
No secondary outcome measures

Overall study start date
13/01/2010

Completion date
30/09/2010

Eligibility

Key inclusion criteria
Adult patients with episodes of major depression

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3600 patients

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)

Sponsor details
Elsenheimer Str. 53
Munich
Germany
80687
+49 (0)89 5709501
marie-laure.escafit-schuelke@de.netgrs.com

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
2011 results presented at DGPPN Kongress 2011 (Laux, G. and C. Steinmann. Antidepressive Behandlung mit Agomelatin in der Hausarztpraxis: Ergebnisse der Studie VIVALDI-Praxis, in DGPPN Kongress. 2011. Berlin. P-011 008).

2012 results presented at DGPPN Kongress 2012 (Laux G, S.C., Escafit-Schülke ML., Behandlung der Depression mit Agomelatin durch den Hausarzt: Ergebnisse der Studie VIVALDI Praxis, in 118. DGIM Kongress. 2012: Wiesbaden. PS139).

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	03/06/2015	07/01/2021	Yes	No
Results article	results	01/04/2017	07/01/2021	Yes	No