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VIVALDI: Valdoxan® improves depressive symptoms and normalises circadian rhythms

Submission date	Recruitment status	[ ] Prospectively registered
26/02/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/05/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/01/2019	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Multi-centre

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
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 measure
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.

Secondary outcome measures
No secondary outcome measures

Overall study start date
16/03/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
8,000 patients/max. 2,000 doctors

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