A Post-Authorization Safety Study of the Use of Intravenous Telavancin (VIBATIV®) in the Clinical Setting (Telavancin PASS)

First published: 06/05/2015

Last updated: 06/05/2015

Study Planned

Administrative details

EU PAS number

EUPAS9669

Study ID

9670

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Bulgaria
- [ ] Croatia

- [ ] Cyprus
- [ ] Czechia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Isle of Man
- [ ] Italy
- [ ] Latvia
- [ ] Liechtenstein
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Slovakia
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

This is a retrospective chart review of patients who have been treated with telavancin (follow-up 6 months post-treatment) in the European Economic Area.

Study status

Planned

Research institutions and networks

Institutions

Clinigen Group

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Boyd Alan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/06/2015

Study start date
Planned: 30/09/2015

Data analysis start date
Planned: 11/03/2016

Date of interim report, if expected
Planned: 11/09/2016

Date of final study report
Planned: 31/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Clinigen Group plc

Study protocol

CLIN_2014_TLV_001 FINAL v2.pdf(376.61 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Drug utilisation

Main study objective:

The primary objective of this study is to assess changes in renal function during and after treatment with telavancin. Adverse Events (AEs) received will be followed up and all efforts will be made to follow up Serious Adverse Events (SAEs) for at least 6 months from first administration of telavancin. Any fatal AE/SAEs will be followed up to collect as much information as possible.

Study drug and medical condition

Name of medicine

VIBATIV

Medical condition to be studied

Staphylococcal infection

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

500

Study design details

Outcomes

To investigate the risks of the following endpoints in order to further characterize the safety of telavancin with respect to renal disorders. The frequency of renal impairment will be investigated, serum creatinine greater than 50% above baseline, serum creatinine greater than 100% above baseline, urine output, need for renal replacement therapy, classification according to RIFLE criteria. Appropriate reporting of all events of special interest, adherence to the SmPC, appropriate usage of the pregnancy sticker and pregnancy testing prior to dosing.

Data analysis plan

All demographic, efficacy and safety variables will be summarised using descriptive statistics and graphs as appropriate. Continuous variables will be summarised by mean, SD, median, minimum, maximum and number of patients. Categorical variables will be summarized using frequency tabulations. Individual data will be presented in patient listings. Medical history and prior and concurrent medications will be summarised and listed. AEs will be classified using the MedDRA classification system. The simple frequency and rate per patient-unit time of AEs will be tabulated by System Organ Class (SOC) and MedDRA Preferred Term. SAEs (including those defined in Section 5.5 of the protocol), AEs leading to discontinuation of telavancin and AEs leading to death will be listed and summarised separately, again by SOC and Preferred Term.

Time to first occurrence of a given AE, time to discontinuation due to AE and time to death will be summarised graphically by Kaplan-Meier curves.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prescription event monitoring, Clinigen sells product direct to hospitals (no wholesalers involved) therefore contact with prescribing physicians will begin from orders placed for telavancin with Clinigen's customer services department.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No

Procedures

Procedure of results generation

CLIN_2014_TLV_001 Statistical Analysis Plan 08Jul14 v2

English (163.33 KB - PDF)

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