Prospective, observational cohort, evaluating the incidence of nephrotoxicity, and other adverse events of interest, in patients treated with the higher recommended teicoplanin loading dose (12 mg/kg twice a day), and comparison with external historical comparator data (OBS13842)

First published: 11/02/2016

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12423

Study ID

35696

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Poland
- [ ] Romania
- [ ] United Kingdom

Study description

The primary objective is to determine the incidence of nephrotoxicity reported in association with teicoplanin higher loading doses of 12 mg/kg twice a day, over the loading dose period (up to day -10). In addition, external historical comparison of nephrotoxicity incidence rates using teicoplanin lower loading dose and vancomycin literature data will be provided.

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

First published: 01/02/2024

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Institution

Multiple centres: 24 centres are involved in the study

Contact details

Study institution contact

Trial Transparency Team Trial Transparency Team Contact-Us@sanofi.com

Study contact

Contact-Us@sanofi.com

Primary lead investigator

Trial Transparency Team Trial Transparency Team

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/07/2015

Actual: 15/07/2015

Study start date

Planned: 31/03/2016

Actual: 22/04/2016

Data analysis start date
Planned: 04/09/2017

Actual: 19/03/2018

Date of interim report, if expected
Planned: 04/12/2017

Actual: 18/06/2018

Date of final study report
Planned: 20/01/2020

Actual: 18/02/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

obs13842-16-1-1-protocol_version 5_11-Jun-2015.pdf(1.3 MB)

obs13842-amended-protocol02.pdf(1.36 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

The primary objective is to determine the incidence of nephrotoxicity reported in association with teicoplanin higher loading doses of 12 mg/kg twice a day, over the loading dose period up to day10.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Antibiotic therapy

Population studied

Short description of the study population

The study population: adults, aged 18 years or older, with infection types for which the higher loading dose of teicoplanin is approved (as per SmPC) and for whom the treating physician intends to prescribe teicoplanin loading dosage 12 mg/kg twice a day.

Inclusion criteria

• Adult patients (aged 18 years or older), with infection types for which the higher loading dose of teicoplanin is approved (as per SmPC), who are prescribed teicoplanin loading doses of 12 mg/kg twice a day by the treating physician.

• Agree to participate and sign the ICF (signed by the patient or by the patient’s

representative).

Exclusion criteria

• Age less than 18 years on the date of inclusion.

• Patients with a history of hypersensitivity to teicoplanin (or to any of the excipients listed in SmPC or to vancomycin.

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

300

Study design details

Outcomes

The primary objective is to determine the incidence of nephrotoxicity reported in association with teicoplanin higher loading doses of 12 mg/kg twice a day, over the loading dose period up to day10. Nephrotoxicity during the maintenance period and the entire study period, Hepatotoxicity, Thrombocytopenia, Hearing and balance/vestibular disorders, renal failure, dialysis and renal replacement therapy, Adverse events/reactions

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Data analysis plan

The primary analysis is the incidence of nephrotoxicity over the loading dose period up to day -10 will be computed with exact binomial 95% confidence interval. Multiple occurrences of nephrotoxicity in the same patient will be

counted only once. A logistic regression will be performed to evaluate covariates associated with the development of selected events. An additional sensitivity analysis will be performed to evaluate the influence of covariates on the occurrence of nephrotoxicity, with known risk factors of nephrotoxicity forced in the model.

Documents

Study results

rdct-obs13842-abstract-PDFA.pdf(245.35 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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