A Multicentre, EU-wide, Non-Interventional Post-Authorisation Study to Assess the Safety and Usage of Delamanid In Routine Medical Practice in Multidrug-Resistant Tuberculosis Patients.

First published: 10/08/2015

Last updated: 29/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10618

Study ID

49710

DARWIN EU® study

No

Study countries

Estonia

France

Germany

Latvia

Lithuania

United Kingdom

Study description

The objectives of the Study are: 1. to monitor the usage of Deltyba in a real-life setting when prescribed as part of an ACR "Appropriate combination regimen" designed by the treating physician, 2. to evaluate treatment outcomes (including clinical effectiveness) as defined by the WHO and / or national guidelines for patients at the end of a full trial treatment period for MDR-TB "Multidrug-resistant tuberculosis" up to 30 months, or earlier if patients are cured, 3. to monitor the safety of Deltyba in a real-life setting when prescribed as part of an ACR designed by the treating physician.

Study status

Finalised

Contact details

Study institution contact

Barbara Eschenbach beschenbach@otsuka-onpg.com

Study contact

beschenbach@otsuka-onpg.com

Primary lead investigator

Barbara Eschenbach

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 02/01/2014

Study start date
Planned: 31/12/2015

Actual: 12/08/2016

Data analysis start date
Planned: 30/06/2022

Actual: 30/09/2021

Date of final study report
Planned: 30/09/2022

Actual: 16/09/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Otsuka Novel Products GmbH

Study protocol

242-12-402 PASS Protocol_Final_Version 3.0_dated 30-Oct-2015.pdf (528.07 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

Safety study (incl. comparative)

If ‘other’, further details on the scope of the study

The study is a key element to generate data on usage of Deltyba in patients with MDR-TB treated in routine medical practice in order to add to the product safety profile.

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

Primary Objective: To monitor usage of Deltyba in a real-life setting when prescibed as part of an appropriate combination regimen (ACR) designed by the treating physician.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-authorisation safety study (PASS)

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J04AK06) delamanid

delamanid

Medical condition to be studied

Pulmonary tuberculosis

Population studied

Short description of the study population

Patients with pulmonary multidrug-resistant tuberculosis prescribed Deltyba from 6 European countries identified between August 2016 and 30 September 2021.

Inclusion criteria:

• Deltyba must be part of an ACR,

• for pulmonary multi-drug resistant TB,

• when an effective treatment regimen could not otherwise be composed for reasons of resistance or tolerability.

Exclusion criteria:

• Age < 18 years

• Concomitant use of drugs that were strong inducers of CYP3A4

• Serum albumin < 2.8 g/dL

• Hypersensitivity to the active substance or to any of the excipients

---

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)

Special population of interest

Other

Special population of interest, other

Patients with pulmonary tuberculosis

Estimated number of subjects

250

Study design details

Outcomes

Usage incl. dosage, compliance and treatment duration of Deltyba, 1. AEs (seriuos / non-serious) 2. Treatment outcomes at the end of observation period (cured, treatment completed, failed, lost to follow-up, died, not evaluated, treatment success)

Data analysis plan

No formal hypothesis are to be tested in this study. Data will be summarised by assessment and visit (where applicable) and dsiplayed by enrolled patients. Descriptive summary statistics for continues variables will include the number of patients (N), mean, SD, median and range. Extent of exposure to Deltyba Number of days patients were exposed to Deltyba will be summarized by duration categories using counts and frequencies.

Documents

Study results

Otsuka 242-12-402_PASS CSR_Amd. 1_Redacted.pdf (3.8 MB)

Otsuka 242-12-402_PASS CSR_Redacted.pdf (3.43 MB)

Study, other information

Otsuka 242-12-402_PASS CSR_Abstract.pdf (197.37 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

The PASS study will collect information routinely documented in patient medical records or NTPs (National tuberculosis programme)

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