A post-marketing database surveillance to investigate the risk of diagnosed peripheral neuropathy and optic nerve disorder events in MRSA patients treated with tedizolid or linezolid in Japan (MK-1986-047)

First published: 14/01/2026

Last updated: 14/01/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000898

Study ID

1000000898

DARWIN EU® study

No

Study countries

Japan

Study description

The main objective of this study is to compare the risk of diagnosed peripheral neuropathy and optic nerve disorder between participants taking tedizolid and those taking linezolid. The study will be conducted to determine whether the risk of diagnosed peripheral neuropathy and optic nerve disorder is higher with tedizolid use compared to linezolid use as a control group.

Study status

Ongoing

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

First published: 01/02/2024

Last updated: 08/07/2025

Institution | Pharmaceutical company

Networks

Medical Information Database NETwork (MID-NET)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 29/05/2025

Study start date

Actual: 09/12/2025

Data analysis start date

Planned: 28/02/2026

Date of final study report

Planned: 17/06/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

E_MK-1986-047_post-marketing database study_Peripheral neuropathy and optic nerve disorder_protocol_final redaction.pdf (1.7 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is an observational cohort study with active comparator new user design, using MID-NET. The study will be conducted using only structured secondary data.

Main study objective:

To compare the risk of diagnosed peripheral neuropathy and optic nerve disorder between participantsnts taking tedizolid and those taking linezolid.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

SIVEXTRO

LINEZOLID

Study drug International non-proprietary name (INN) or common name

TEDIZOLID PHOSPHATE

Anatomical Therapeutic Chemical (ATC) code

(J01XX08) linezolid

linezolid

(J01XX11) tedizolid

tedizolid

Medical condition to be studied

Optic nerve disorder

Additional medical condition(s)

Peripheral neuropathy

Population studied

Short description of the study population

Methicillin-resistant Staphylococcus aureus (MRSA) participants who are treated with tedizolid or linezolid between 21-Aug- 2018 and 31-Mar-2025.

Key inclusion criteria include but are not limited to:
1. Has a new prescription date (index date) for tedizolid or linezolid during the cohort entry period 21-Aug-2018 to 31-Mar-2025.
2. Confirmed diagnosis of MRSA and confirmed diagnosis of indications for both tedizolid and linezolid in the same month or previous month of the index date.

Key exclusion criteria include but are not limited to:
1. Do not have 60 days lookback period prior to the index date.

2. Have prescriptions for both tedizolid and linezolid on the same index date.
3. Have one or more events of peripheral neuropathy and optic nerve disorder within 60 days lookback period.
4. Have prescription records for tedizolid or linezolid only on the index date.

Age groups

- **In utero**
- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
- Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

200

Study design details

Setting

The study population is MRSA participants who were treated with tedizolid or linezolid between 21-Aug-2018 and 31-Mar-2025 in Japan. The study will be conducted using only structured secondary data collected from MED-NET.

Comparators

The group of participants who are newly prescribed/exposed to tedizolid during the cohort entry period (21-Aug-2018 to 31-Mar-2025) will be considered as the tedizolid group. The group of participants who newly start linezolid during the cohort entry period (21-Aug-2018 to 31-Mar-2025) will be considered as the linezolid group.

Outcomes

The primary outcomes of interest are as follows:
Peripheral neuropathy is defined as cases meeting the following two conditions.
1. A confirmed diagnosis of peripheral neuropathy(ICD-10 code).
2. In the same month as, the month prior to, or the month after the confirmed diagnosis of peripheral neuropathy, a treatment drug for peripheral neuropathy or pain was prescribed, a test related to peripheral neuropathy was performed, or blood purification therapy for immune neuropathy was performed.

Optic nerve disorder is defined as cases meeting the following two conditions.
1. A confirmed diagnosis of optic nerve disorder(ICD-10 code).
2. In the same month as, the month prior to, or the month after the confirmed diagnosis of optic nerve disorder, vitamin B12 or corticosteroids were prescribed, or any of the relevant tests for optic nerve disorder (general, outpatient, or imaging tests) were performed.

Data analysis plan

Incidence rates of peripheral neuropathy and optic nerve disorder and binomial confidence intervals will be calculated descriptively for tedizolid and linezolid groups separately. The number and percentage of participants with peripheral neuropathy and optic nerve disorder will be calculated. For all participants , the exposure time starts the day after the initiation of treatment date.

If there are 10 or more events observed for each treatment group, crude odds ratios and 95% confidence interval (CI) will be estimated to be using logistic regression models, to compare the risk of peripheral neuropathy and optic nerve disorder between the tedizolid group and linezolid group

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 source(s), other

Medical Information Database NETwork (MID-NET)

Data sources (types)

Drug registry

Electronic healthcare records (EHR)

Non-interventional study

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

Unknown