A post-marketing database surveillance to investigate the risk of diagnosed lactic acidosis events in MRSA patients treated with tedizolid or linezolid in Japan (MK-1986-046)

First published: 14/01/2026

Last updated: 26/10/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000894

Study ID

1000000894

DARWIN EU® study

No

Study countries

Japan

Study description

The main objective of this study is to compare the risk of diagnosed lactic acidosis events in patients with Methicillin-resistant Staphylococcus aureus (MRSA) taking either tedizolid or linezolid in Japan. The study will be conducted to determine whether the risk of diagnosed lactic acidosis is higher with tedizolid use compared to linezolid.

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

Actual: 28/02/2026

Date of final study report

Planned: 26/02/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

MK-1986-046_post-marketing database study_Lactic acidosis_protocol_final-redactiond.pdf (1.66 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:

The main objective is to compare the risk of diagnosed lactic acidosis between those patients taking tedizolid and those patients taking linezolid for MRSA.

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

Lactic acidosis

Population studied

Short description of the study population

The study population is MRSA patients who were treated with tedizolid or linezolid between 21-Aug-2018 and 31-Mar-2025 in Japan.

Key inclusion criteria include:

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:

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 lactic acidosis within 14 days prior to the index date.
4. Have prescription records for tedizolid or linezolid only on the index date.

Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - 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)
- **Adult and elderly population (≥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 patients 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 MID-NET.

Comparators

The group of patients 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 patients 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 outcome of interest in the study is lactic acidosis. Tests for lactic acidosis (pH and lactate test) are performed on the same day and both are abnormal values (pH < 7.35, lactate test > 5 mmol/L).

Data analysis plan

Incidence rates of lactic acidosis and binomial confidence intervals will be calculated descriptively for tedizolid and linezolid groups separately. The number and percentage of lactic acidosis will be calculated. For all patients, 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% CI will be estimated using logistic regression models, to compare the risk of lactic acidosis between the tedizolid group and linezolid group. Basic statistics on the surveillance population will be presented as n (%), mean ± standard deviation (SD), or median (interquartile range [IQR]), as appropriate.

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)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

CDM Mappings

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown