

# 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:** 26/06/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000894

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### Study ID

1000000894

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### DARWIN EU® study

No

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### Study countries

 Japan

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## 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.

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## 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**

Clinical Trials Disclosure Merck Sharp & Dohme LLC  
ClinicalTrialsDisclosure@msd.com

Study contact

[ClinicalTrialsDisclosure@msd.com](mailto:ClinicalTrialsDisclosure@msd.com)

### **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

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### **Study start date**

Actual: 09/12/2025

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### **Data analysis start date**

Planned: 28/02/2026

Actual: 28/02/2026

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### **Date of final study report**

Planned: 19/03/2027

## 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

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### **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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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

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

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**Anatomical Therapeutic Chemical (ATC) code**

(J01XX08) linezolid

linezolid

(J01XX11) tedizolid

tedizolid

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**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.

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## **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)
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## **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.

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### **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.

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### **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).

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### **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  $\pm$  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)

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### **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

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### **Check completeness**

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

Unknown