Prospective cohort study to describe the natural history of Epstein-Barr virus infection

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000914

Study ID

1000000914

DARWIN EU® study

No

Study countries

- Australia
- Canada
- Denmark
- Japan

United States

Study description

This is a prospective cohort study to describe the natural history of Epstein-Barr virus (EBV) infection (including outcomes up to 6 years). The primary objectives of the study are to estimate EBV seroprevalence by study site at screening and, among participants who are seronegative at screening, estimate the incidence of (1) EBV seroconversion and (2) infectious mononucleosis (IM) during follow-up by study site.

Study status

Ongoing

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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Institution | Pharmaceutical company

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: 10/12/2024

Study start date
Actual: 26/09/2025

Data analysis start date
Planned: 31/05/2031

Date of final study report
Planned: 31/12/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Evaluation of patient-reported outcomes

Method development or testing

Data collection methods:

Primary data collection

Study design:

This is a prospective cohort study.

Main study objective:

The primary objectives of the study are to estimate EBV seroprevalence by study site at screening and, among participants who are seronegative at screening, estimate the incidence of (1) EBV seroconversion and (2) infectious mononucleosis (IM) during follow-up by study site.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Epstein-Barr virus infection

Population studied

Short description of the study population

High school students aged 14-17 and university first-year students aged 18-20 in the U.S., Canada, Denmark, Japan, and Australia.

Key Inclusion Criteria include:
High school student population: Has at least one academic year of school remaining and is aged 14-17 years
University student population: Is a first-year university student aged 18-20 years

At Follow-up:
Meets all screening inclusion criteria and is EBV-seronegative at screening
Has at-home access to an internet-connected device that they could use daily for 2 weeks

Key Exclusion Criteria include:
Has abnormalities of the spleen or a history of splenectomy (by self-report)
Is receiving immunosuppressive drugs or therapy, including but not limited to chemotherapeutic agents used to treat cancer or other conditions (for example, autoimmune disease) and interventions associated with organ or bone marrow transplantation (by self-report)
Regularly receives courses of daily systemic corticosteroids (equivalent of daily dose of prednisone or ≥20 mg/d) (by self-report)
Has a known acquired or congenital condition that affects the immune system and/or the ability to fight infections (by self-report)
Received immunoglobulins and/or any blood products in the 2 months before enrollment or are expected to receive such products in the future (by self-report)
Previously received an experimental EBV vaccine

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 65 years)

- Adults (18 to < 46 years)

Estimated number of subjects

4450

Study design details

Setting

High school students aged 14-17 and university first-year students aged 18-20 in the U.S., Canada, Denmark, Japan, and Australia.

Outcomes

The outcomes for this study are EBV serostatus at screening, EBV seroconversion and infectious mononucleosis.

Data analysis plan

EBV seroprevalence will be calculated as the number of EBV-seropositive persons out of the total number with a valid EBV serology result obtained from a screening visit sample, stratified by site.

For each primary objective outcome, cumulative incidence will be calculated using Kaplan-Meier methods. The incidence rate will be calculated as the number of incident outcomes divided by the amount of person-time at risk of developing the outcome.

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)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Unknown

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction

after creation of study variables