Post-Licensure Observational Study of the Long-term Effectiveness of ZOSTAVAX(TM) (V211-024)

First published: 26/05/2017

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17502

Study ID

50065

DARWIN EU® study

No

Study countries

United States

Study description

This large-scale, postlicensure observational study is being conducted to assess the long-term effectiveness (over 10 years) of ZOSTAVAX(TM) (live zoster vaccine) and the real-world impact of zoster vaccination on the epidemiology of herpes zoster (HZ) when administered in routine use to people 50 years of age or older.

Study status

Finalised

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

Large integrated healthcare system in the United States

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

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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: 30/06/2010

Study start date

Actual: 15/05/2012

Data analysis start date

Planned: 30/09/2020

Actual: 16/10/2020

Date of interim report, if expected

Planned: 31/12/2016

Actual: 15/12/2016

Date of final study report

Planned: 31/12/2020

Actual: 07/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

V211-024+Protocol_final-redaction.pdf (1.51 MB)

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)

Other study registration identification numbers and links

NCT01600079

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The objective of the study is to assess the effectiveness of the vaccine against HZ and postherpetic neuralgia (PHN) in people vaccinated at 50 years of age or older, overall, by age at vaccination, and by time since vaccination.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, open study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07BK02) zoster, live attenuated

zoster, live attenuated

Medical condition to be studied

Herpes zoster

Post herpetic neuralgia

Population studied

Short description of the study population

The study cohort included KPNC members diagnosed with herpes zoster receiving ZOSTAVAX™ on the day they become age-eligible. The study cohort refreshed annually to include members of aged 50 years or older.
Inclusion criteria:
- The study cohort was limited to KPNC members with continuous KPNC membership since becoming age-eligible for ZOSTAVAX™ and with 12 months of continuous enrollment in KPNC before their study start date (referred to as the “baseline period”).
- Continuous membership since becoming age-eligible ensured accurate information on vaccination and HZ occurrence.
- The 12-month baseline period was also needed for the assessment of several study variables, such as immune compromise status and co-morbid conditions, and for the evaluation of certain exclusion criteria.

Exclusion criteria:
- a HZ diagnosis in the baseline period
- receipt of ZOSTAVAX™ prior to study start date

- joining KPNC after age-eligibility (i.e., individuals ≥60 years of age who joined KPNC after May 2006 and individuals ≥50 years of age who joined KPNC after March 2011).

Age groups

- 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 herpes zoster

Estimated number of subjects

30.000

Study design details

Outcomes

Herpes zoster, Postherpetic neuralgia

Data analysis plan

Vaccine effectiveness is estimated by comparing the incidence of HZ and PHN in vaccinated and unvaccinated individuals through Cox regression models. Vaccine effectiveness is estimated by Cox proportional hazards models utilizing stratification on birth year, and adjusted for time-fixed and time-varying covariates.

Documents

Study results

V211-024v01-final-report-dec-2020_Final Redaction.pdf (6.47 MB)

Study report

V211-024+Interim+Report+ENCePP_final-redaction.pdf (4.58 MB)

Study publications

Klein NP, Bartlett J, Fireman B, Marks MA, Hansen J, Lewis E, Aukes L, Saddier ...

Baxter R, Bartlett J, Fireman B, Marks M, Hansen J, Lewis E, Aukes L, Chen Y, K...

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)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Medical chart review

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