212853 - Shingrix for intramuscular injection Drug Use Investigation

First published: 26/04/2022

Last updated: 28/05/2026

Study Finalised

Administrative details

EU PAS number

EUPAS46662

Study ID

46663

DARWIN EU® study

No

Study countries

Japan

Study description

The purpose of this prospective, descriptive, multi-center, drug utilization study is to assess the safety of Shingrix vaccine when administered in Japanese adults for the first time.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Call Center EU Clinical Trials

Vx.publicdisclosureglobal@gsk.com

Study contact

Vx.publicdisclosureglobal@gsk.com

Primary lead investigator

Call Center EU Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 14/09/2020

Actual: 14/09/2020

Study start date
Planned: 31/10/2020

Actual: 09/10/2020

Date of final study report
Planned: 30/04/2026

Actual: 28/04/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-212853-protocol-redact.pdf (176.84 KB)

Protocol Anonymised.pdf (258.15 KB)

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:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To assess the presence or absence of issues and concerns related to safety of Shingrix under practical use conditions.

Study drug and medical condition

Medicinal product name

SHINGRIX

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

HERPES ZOSTER VACCINE (RECOMBINANT, ADJUVANTED)

Anatomical Therapeutic Chemical (ATC) code

(J07BK03) zoster, purified antigen

zoster, purified antigen

Medical condition to be studied

Herpes zoster

Population studied

Short description of the study population

Persons vaccinated with Shingrix for the first time, for the purpose of preventing zoster.

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

7500

Study design details

Setting

Medical institutes, mainly internal medicine, where agreed to be participate in this investigation (approximately 1,000 sites)

Outcomes

Occurrence of Solicited adverse events and Unsolicited adverse events

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Data analysis plan

Analytical methods include:

- Safety: calculate incidence proportion of vaccine related adverse reaction.
- Consideration of covariates: consideration for covariates which may relate to safety (incidence proportion of vaccine related adverse reaction) by calculation odds ratio and 95% confidence interval, figure out forest-plot if necessary.

Documents

Abstract of study report

Study Report Synopsis Anonymised.pdf (304.75 KB)

Study report

Clinical Study Report Anonymised.pdf (11.84 MB)

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)

Other

Data sources (types), other

Prospective patient-based data collection

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