212853 - Shingrix for intramuscular injection Drug Use Investigation

First published: 26/04/2022

Last updated: 04/04/2024

Study Ongoing

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

Ongoing

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: 15/04/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

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

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Safety study (incl. comparative)

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

Name of medicine

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

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

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.

Data management

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