212853 - Shingrix for intramuscular injection Drug Use Investigation

First published: 26/04/2022
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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/46663

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 institution and networks

Institutions

GlaxoSmithKline (GSK)
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Institution

Contact details

Study institution contact
Call Center EU Clinical Trials
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 list

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

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

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