Inactivated varicella zoster vaccine and herpes zoster

First published: 17/05/2021

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Study Finalised

Administrative details

EU PAS number

EUPAS41039

Study ID

41040

DARWIN EU® study

No

Study countries

Germany

Study description

Patients with a prescription for inactivated varicella zoster vaccine are compared to patients with a prescription for pneumococcal vaccine and patients with a prescription for live attenuated varicella zoster vaccine. Patients

must have a minimum observation time of 180 days before and 28 days after the first prescription for the vaccine. Patients are followed for herpes zoster events during 28 days after the first prescription. Results are stratified by gender, age group, a history of varicella or herpes zoster, and a history of immunodeficiency or immunosuppression.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Karin Hedenmalm

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 26/11/2019

Actual: 26/11/2019

Study start date
Planned: 08/01/2020

Actual: 08/01/2020

Data analysis start date
Planned: 08/01/2020

Actual: 08/01/2020

Date of final study report
Planned: 12/02/2020

Actual: 12/02/2020

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Occurrence of herpes zoster

Data collection methods:

Secondary use of data

Main study objective:

The main objective of the study was to compare the occurrence of herpes zoster events up to 28 days after a vaccination prescription for inactivated varicella zoster vaccine vs. pneumococcal vaccine and live attenuated varicella zoster vaccine.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Descriptive

Study drug and medical condition

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

RECOMBINANT VARICELLA ZOSTER VIRUS GLYCOPROTEIN E

Population studied

Short description of the study population

Definition of study population:

• Patients 2-99 years, both genders

• Disease codes:

o History of varicella: ICD 10 code B01 (includes events recorded 1-28 days after the vaccination prescription if the diagnosis certainty is ‘condition after’)

o History of herpes zoster: ICD 10 code B02 (includes events recorded 1-28 days after the vaccination prescription if the diagnosis certainty is ‘condition after’)

o History of immunodeficiency: ICD 10 codes B20-B24, C81-C96 or D80-D84

o Vaccination date: ICD 10 codes Z23-Z27

• Treatment codes:

o Treatment with inactivated varicella zoster vaccine:

 EphMRA ATC code J07E2, therapy name contains ‘shingrix’

o Treatment with live attenuated varicella zoster vaccine:

 EphMRA ATC code J07E2, therapy name not contains ‘shingrix’

o Treatment with pneumococcal vaccine:

 EphMRA ATC code J07D1:

• Conjugated vaccine: Molecule name contains ‘conjugated’ or therapy name contains ‘synflorix’

• Unconjugated vaccine: Molecule name not contains ‘conjugated’ and therapy name not contains ‘synflorix’

o Prior immunosuppressive treatment within 90 days prior vaccination prescription:

 EphMRA ATC code L01 and L04 (excluding L01X1 ‘mistletoe extracts’)

o Prior immunosuppressive treatment or systemic corticosteroid treatment within 90 days prior vaccination prescription:

 EphMRA ATC code L01 L04 and H02 (excluding L01X1 ‘mistletoe extracts’)

• Exclusion criteria applied: Patients are excluded in case of same day prescription for inactivated varicella zoster vaccine and either live attenuated varicella zoster vaccine or pneumococcal vaccine. Patients are required to have a minimum observation period of 180 days prior to the first vaccination prescription and at least 28 days of follow-up after the first vaccination prescription. A separate sensitivity analysis requires patients to have at least 56 days of follow-up.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)

- Adults (85 years and over)

Estimated number of subjects

10.000

Study design details

Data analysis plan

The study was descriptive. The occurrence of a herpes zoster event within 28 days after a vaccination prescription was studied. Results were stratified by gender, age group, a history of varicella or herpes zoster and a history of immunodeficiency or immunosuppression.

Documents

Study results

RDA-Shingrix-Herpes-Zoster-Results-20200212_IQVIA.pdf (826.06 KB)

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 source(s), other

IQVIA Disease Analyzer Germany

Data sources (types)

Electronic healthcare records (EHR)

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