Inactivated varicella zoster vaccine and herpes zoster

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Administrative details

PURI https://redirect.ema.europa.eu/resource/41040
EU PAS number
EUPAS41039
Study ID 41040
DARWIN EU® study
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

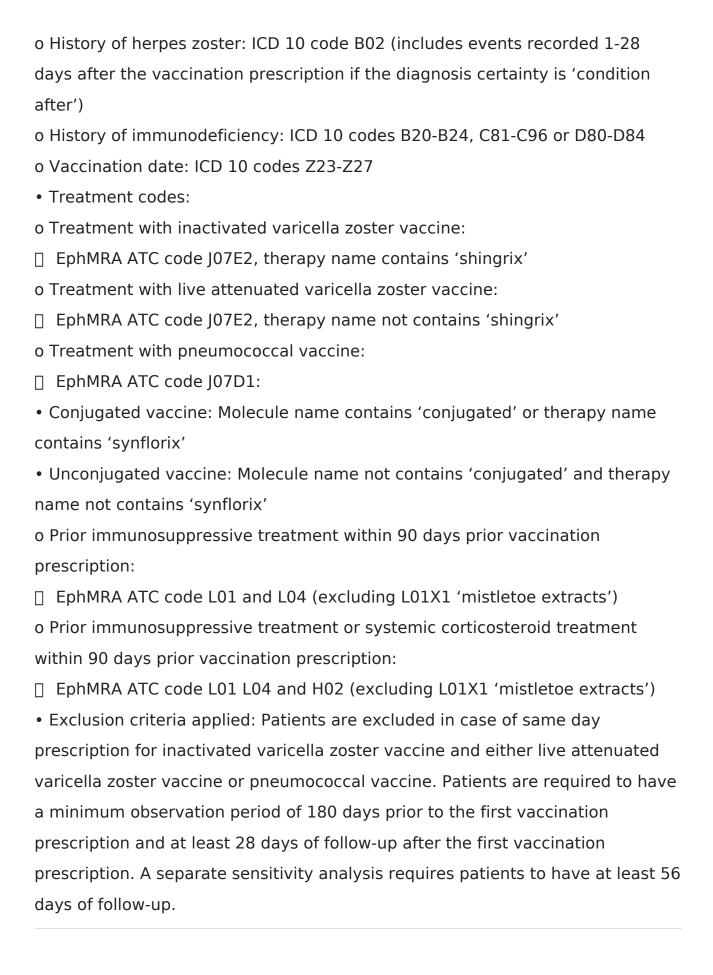
Population studied

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')



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

10000

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

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