Prevalence of immunocompromised patients with a diagnosis of cytomegalovirus infection

First published: 21/06/2023

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Study Finalised

Administrative details

EU PAS number

EUPAS104331

Study ID

104332

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany

Study description

A descriptive study of yearly prevalence of immunocompromised patients and those immunocompromised with cytomegalovirus (CMV).

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Chantal Quinten

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 03/02/2022

Actual: 03/02/2022

Study start date
Planned: 03/02/2022

Actual: 03/02/2022

Date of final study report
Planned: 05/09/2022

Actual: 02/09/2022

Sources of funding

- EMA

Study protocol

Analysis Plan_CMV_For_Publication_CLEAN.pdf (290.83 KB)

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The primary objectives were to estimate the prevalence of immunocompromised patients, and immunocompromised patients who were diagnosed with CMV.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive study

Study drug and medical condition

Medical condition to be studied

Cytomegalovirus mononucleosis

Cytomegalovirus infection

Population studied

Short description of the study population

The study population included patients with cytomegaloviral infections aged ≥ 1 year visiting general practices in France and Germany between 2016 and 2020, identified from the IQVIA™ Disease Analyser database.

Age groups

Infants and toddlers (28 days – 23 months)

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)

Special population of interest

Immunocompromised

Other

Special population of interest, other

Patients with cytomegaloviral infections

Estimated number of subjects

350

Study design details

Data analysis plan

Prevalence of immunocompromised patients: the numerator consisted of immunocompromised patients during the yearly time period. Patients with an underlying condition at any time prior or with a prescription of immunosuppressive therapy 90 days prior the assessment period were included, the denominator consisted of patients that were observable for at least one day during the respective year. Prevalence of immunocompromised patients with CMV: the numerator consisted of immunocompromised diagnosed with CMV during the yearly time period. Patients with an underlying condition any time prior the CVM diagnoses or with a prescription for immunosuppressive therapy 90 days prior the CMV diagnoses date were included, the denominator consisted of patients that were observable for at least one day during the respective year. In both cases the observability for a patient started on the date of the first visit to the practice and ended on the date of the last visit to the practice.

Documents

Study results

Final-Report-Results-Simple study_CMV_20221021_For_Publication_CLEAN_final.pdf (417.89 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)

IQVIA Disease Analyzer Germany

Disease Analyzer - OMOP

Data sources (types)

Drug dispensing/prescription data

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