SEROLOGICAL EVOLUTION OF PRIMARY INFECTION BY EPSTEIN-BARR VIRUS IN CHILDREN

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Study Finalised

Administrative details

EU PAS number

EUPAS32464

Study ID

32465

DARWIN EU® study

No

Study countries

Spain

Study description

The aim of this study was to know epidemiological, clinical and laboratory characteristics of primary infection by Epstein-Barr virus (EBV) in healthy children from our region. In a second prospective phase, we assessed serological and clinical evolution after primary infection and calculated the probability of not creating antibodies to a Epstein-Barr Nuclear Antigen (EBNA).We included patients with positive or indeterminate results of the EBV-VCA IgM test over a period of 22 months. We included cases identified through the Microbiology Laboratory which is the regional referral laboratory coordinating services for the public health catch-ment área of Xàtiva-Ontinyent in the province of Valencia in Spain, with a population of 204.623 inhabitants (2013 census) of whom 30.636 were aged less tan 15 years. We collected epidemiological, clinical and laboratory data from electronic health records following the protocol for data access and confidentiality of our hospital. Then, we visited patients at 6, 12, 18 and 24 months after the primary infection by EBV. We reported clinical and serological data from blood tests (VCA IgM, VCA IgG, EBNA IgG, Early Antigen IgG) in each visit, and according to the results, DNA detection by PCR test at 12,18 and 24 months after infection.

Study status

Finalised

Research institutions and networks

Institutions

Health Department Xàtiva-Ontinyent

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Monica Garcia Peris

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 09/01/2013

Study start date

Actual: 01/02/2013

Data analysis start date

Actual: 19/06/2017

Date of final study report

Actual: 17/09/2018

Sources of funding

- Other

More details on funding

Health Department Xàtiva-Ontinyent

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Epidemiological, clinical and laboratory characteristics

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To describe serological evolution of primary infection by EBV in immunocompetent children and calculated the probability of not create EBNA antibodies

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series

Population studied

Short description of the study population

Patients with positive or indeterminate results of the Epstein-Barr virus (EBV)-VCA IgM test over a period of 22 months

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Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

94

Study design details

Outcomes

The probability of not create EBNA antibodies was 48% at 6 months, 25% at 1 year and 10% at 2 years after primary infection. Only a few patients didn´t have humoral response with EBNA antibodies or created them lately. Anyone of them had symptoms of chronic active EBV infection. Female sex associated with a delay in disappear VCA IgM antibodies and in create EBNA antibodies.

Data analysis plan

We used a Poisson regression variation to determine the influence of variables in time until seroconversión. The statistical model considered the losts of patients along the study.

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 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

Unknown