

A long-term follow up of a phase II open, randomised, controlled study to evaluate the safety and immunogenicity of a paediatric dose (0.25 ml) and the standard dose (0.5 ml) of Epaxal® with reference to Havrix Junior® in healthy children and adolescents (more than or equal to 12 months to 16 years of age), using a 0/6 month schedule

Submission date

21/11/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

14/12/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

05/01/2021

Condition category

Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01405677

Protocol serial number
EPA 001 FU

Study information

Scientific Title

A long-term follow up of a phase II open, randomised, controlled study to evaluate the safety and immunogenicity of a paediatric dose (0.25 ml) and the standard dose (0.5 ml) of Epaxal® with reference to Havrix Junior® in healthy children and adolescents (more than or equal to 12 months to 16 years of age), using a 0/6 month schedule

Acronym
EPA

Study objectives

The long term protection conferred by the pediatric dose of Epaxal® (12 IU) is comparable to that conferred by the standard dose of Epaxal® (24 IU).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received by local ethics committees (Comite voor Medische Ethiek, Universitair Ziekenhuis Antwerpen [21/09/2006] and the Commissie Medische Ethiek, Sint-Vincentiusziekenhuis, Antwerp [26/10/2006]).

Primary study design
Interventional

Study design
Follow up to an open, randomised, controlled trial (EPA 001)

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Hepatitis A

Interventions
Interventions made in the primary study (EPA 001):
1. 0.25 ml Epaxal (12 IU hepatitis A antigen)
2. 0.50 ml Epaxal (24 IU hepatitis A antigen)
3. Comparator vaccine

From each subject willing to participate in this follow up study we will obtain:
First yearly visit: informed consent and circa 5 ml of veinous blood.
Four remaining yearly visits: circa 5 ml of veinous blood.
For each sample of blood the anti-Hepatitis A Virus (HAV) antibody titres using an Enzyme-Linked ImmunoSorbent Assay (ELISA) wil be tested.
Computer modeling of long term protection.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Epaxal®

Primary outcome(s)

Proportion of subjects seroprotected five years after booster vaccination

Key secondary outcome(s)

Individual antibody titres and Geometric Mean antibody Titres (GMTs) one, two, three, four, and five years after booster vaccination.

Completion date

01/03/2011

Eligibility**Key inclusion criteria**

1. Healthy children and adolescents
2. More than or equal to 12 months to 16 years of age
3. Enrolled and randomised in the primary study (EPA 001) and having received two doses of the study vaccines

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

12 Months

Upper age limit

16 Years

Sex

Not Specified

Total final enrolment

271

Key exclusion criteria

1. Subjects NOT enrolled and randomised in the primary study (EPA 001)
2. Subjects NOT having received two doses of the study vaccines

Date of first enrolment

01/12/2006

Date of final enrolment

01/03/2011

Locations**Countries of recruitment**

Belgium

Study participating centre

Centre for the Evaluation of Vaccination

Antwerp

Belgium

2610

Sponsor information**Organisation**

Berna Biotech AG, a Crucell Company (Switzerland)

Funder(s)**Funder type**

Industry

Funder Name

Berna Biotech AG, a Crucell Company (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2015	05/01/2021	Yes	No