

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	<input type="checkbox"/> Prospectively registered
Registration date 14/12/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/01/2021	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT01405677

Secondary identifying numbers

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]).

Study design

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

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

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) will be tested.

Computer modeling of long term protection.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Epaxal®

Primary outcome measure

Proportion of subjects seroprotected five years after booster vaccination

Secondary outcome measures

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

Overall study start date

01/12/2006

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

Age group

Child

Lower age limit

12 Months

Upper age limit

16 Years

Sex

Not Specified

Target number of participants

308

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)

Sponsor details

c/o Christian Herzog, MD
Rehhagstrasse 79
Bern
Switzerland
3018

Sponsor type

Industry

Website

<http://www.crucell.com/>

Funder(s)

Funder type

Industry

Funder Name

Berna Biotech AG, a Crucell Company (Switzerland)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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