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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

Registration date
14/12/2006

Last Edited
05/01/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Pierre Van Damme, MD

Contact details
Centre for the Evaluation of Vaccination
World Health Organization Collaborating Centre for Control and Prevention of Viral Hepatitis
Unit of Epidemiology and Social Medicine
University of Antwerp
Universiteitsplein 1
Antwerp
Belgium
2610

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 Etiek, 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

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 (Swtizerland)

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