ISRCTN91009479 https://doi.org/10.1186/ISRCTN91009479

A phase III 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 comparator vaccine in healthy children and adolescents (12 months to 16 years of age inclusive), using a 0/6 month schedule

Submission date
25/10/2006

Recruitment status
No longer recruiting

Registration date
14/11/2006

Overall study status
Completed

Last Edited
06/01/2021

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

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Additional identifiers

Protocol serial number

EPA 006

Study information

Scientific Title
A phase III 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 comparator vaccine in healthy children and adolescents (12 months to 16 years of age inclusive), using a 0/6 month schedule

Acronym
EPA

Study objectives
The pediatric dose of Epaxal (12 IU) is as immunogenic as the standard Epaxal® dose (24 IU).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Scientific Ethics Committee of the Health Service of Valdivia, Chile (Comité Etico Cientifico, Servicio de Salud, Valdivia, Chile) Hospital Base on the 28 September 2006.

Study design
Open, randomised, controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
1) 0.25 ml Epaxal (12 IU hepatitis A antigen)
2) 0.50 ml Epaxal (24 IU hepatitis A antigen)
3) Comparator vaccine

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Epaxal®

Primary outcome(s)

Proportion of subjects seroprotected (seroprotection defined as anti-HAV antibody titre greater or equal to 10 mIU/mL) one month after vaccination

Key secondary outcome(s))
1. Proportion of subjects seroprotected (seroprotection defined as anti-HAV antibody titre greater or equal to 10 mIU/mL) one month after booster vaccination.
2. Proportion of subjects with local and/or systemic adverse events after each vaccination.

Completion date
01/08/2007

Eligibility

Key inclusion criteria
Healthy children aged 12 months to 16 years inclusive.

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
360

Key exclusion criteria
1. Chronic administration (defined as more than 14 days) of immunosuppressants or other immune-modifying drugs within six months prior to the first vaccine dose (for corticosteroids, this will mean prednisone, or equivalent, 0.5 mg/kg/day. Inhaled and topical steroids are allowed)
2. Previous vaccination against Hepatitis A Virus (HAV)
3. Seropositive for anti-HAV antibodies (screening Enzyme-Linked Immuno-Sorbent Assay [ELISA])
4. Any confirmed or suspected immunosuppressive or immunodeficient condition, including Human Immunodeficiency Virus (HIV) infection

Date of first enrolment
01/11/2006

Date of final enrolment
01/08/2007

Locations

Countries of recruitment
Chile

Study participating centre
Gastroenterólogo
Valdivia
Chile
6670172

Sponsor information

Organisation
Berna Biotech AG (Switzerland)

Funder(s)

Funder type
Industry

Funder Name
Berna Biotech AG (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	08/11/2011	06/01/2021	Yes	No