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# 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

**EudraCT/CTIS number**

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

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

### Secondary outcome measures
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.

### Overall study start date
01/11/2006

### Completion date
01/08/2007

## Eligibility

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

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
12 Months

### Upper age limit
16 Years

### Sex
Not Specified

### Target number of participants

360

### 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)

### Sponsor details
c/o Christian Herzog, MD
Berna Biotech Ltd, a Crucell Company
Rehhagstrasse 79
Bern
Switzerland
3018

**Sponsor type**
Industry

**Website**
http://www.bernabiotech.com/home/

# Funder(s)

**Funder type**
Industry

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