# Safety and immunogenicity of concomitant administration of a virosomal hepatitis A vaccine (Epaxal®) with DTP, aHib, IPV, OPV and MMR vaccines versus non-concomitant administration in 12 to 15 month-old children

Submission date	Recruitment status	Prospectively registered		
31/01/2006	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
10/03/2006	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
11/01/2021	Infections and Infestations			

# Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Prof Ron Dagan

#### Contact details

Pediatric Infectious Diseases Unit Soroka University Medical Center P O Box 151 Beer Sheva Israel 84101

## Additional identifiers

Protocol serial number EPA 004

# Study information

## Scientific Title

Safety and immunogenicity of concomitant administration of a virosomal hepatitis A vaccine (Epaxal®) with DTP, aHib, IPV, OPV and MMR vaccines versus non-concomitant administration in 12 to 15 month-old children

## Acronym

**EPA** 

## **Study objectives**

Epaxal® co-administered with Diphtheria Tetanus Petusis (DTP), activated haemophilus influenzae type B (aHib), Inactivated Polio Vaccine (IPV), Oral Poliovirus Vaccine (OPV) and Measles Mumps Rubella (MMR) vaccines is as immunogenic as when given alone

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved by the Helsinki Committee of the Pediatric Infectious Diseases Unit, Soroka University Medical Center, November 2004, reference number: 20040507

## Study design

Open, randomised, controlled

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Hepatitis A

#### **Interventions**

- 1. Epaxal® and concomitant administration of DTP, aHib, IPV, OPV and MMR vaccines
- 2. Epaxal® followed by DTP, aHib, IPV, OPV and MMR vaccines one month later
- 3. Comparator Hepatitis A Virus (HAV) vaccine and concomitant administration of HAV vaccines

## Intervention Type

Drug

#### Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Vaccines: 1. Epaxal® 2. Diphtheria Tetanus Petusis (DTP) 3. Activated haemophilus influenzae type B (aHib) 4. Inactivated Polio Vaccine (IPV) 5. Oral Poliovirus Vaccine (OPV) 6. Measles Mumps Rubella (MMR)

## Primary outcome(s)

Percentage of subjects seroprotected (anti-HAV titre >/=10 mIU/ml) one month after vaccination

## Key secondary outcome(s))

- 1. Percentage of subjects with antibodies against each co-administered antigen one month after vaccination
- 2. Incidence of adverse events reported after each vaccination

## Completion date

26/01/2006

# **Eligibility**

## Key inclusion criteria

Healthy children between 12 and 15 months old at the time of vaccination

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Child

## Lower age limit

12 months

## Upper age limit

15 months

### Sex

All

## Total final enrolment

322

## Key exclusion criteria

- 1. Children that have not received three documented doses of DTP, aHib and polio vaccines during infancy
- 2. Children that have received a documented dose of MMR during infancy
- 3. Previous vaccination against hepatitis A
- 4. Any confirmed or suspected immunosuppressive or immunodeficient condition

#### Date of first enrolment

26/12/2004

### Date of final enrolment

26/01/2006

## Locations

## Countries of recruitment

Israel

Study participating centre
Pediatric Infectious Diseases Unit
Beer Sheva
Israel
84101

# Sponsor information

## Organisation

Berna Biotech Ltd (Switzerland)

# Funder(s)

Funder type

Industry

## **Funder Name**

Berna Biotech Ltd

# **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	01/09/2007	11/01/2021	Yes	No