

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

31/01/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

10/03/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

11/01/2021

Condition category

Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Primary study design

Interventional

Study design

Open, randomised, controlled

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