ISRCTN82277382 https://doi.org/10.1186/ISRCTN82277382

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

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

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

Overall study start date
26/12/2004

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

Age group
Child

Lower age limit
12 Months

Upper age limit
15 Months

Sex
Both

Target number of participants
300

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)

Sponsor details
Rehhagstrasse 79
Bern
Switzerland
CH-3018

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Berna Biotech Ltd

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