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A phase II, double blind randomised, placebo controlled study to assess the safety reactogenicity and immunogenicity of three doses of GSK Biologicals (South Africa)

Submission date
25/11/2005

Recruitment status
No longer recruiting

Registration date
25/11/2005

Overall study status
Completed

Last Edited
29/01/2008

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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

N/A

Study information

Scientific Title

Acronym
Rota014

Study objectives
This study was undertaken to identify whether the immunogenicity of live Oral Poliovirus (OPV) vaccine was affected by the concomitant administration of the candidate Human Rotavirus (HRV) vaccine and also to assess the safety of the candidate HRV vaccine given concomitantly with poliovirus vaccine (OPV or IPV). The study was conducted in two parts, the first part (subset enrolled before the start of the 2002 Rotavirus [RV] season) and the second part of the study (subset enrolled after the end of the 2002 rotavirus season).

Objective:
To demonstrate that co-administering HRV vaccine with OPV does not induce a significant decrease in poliovirus immune response one month after the third dose of polio vaccine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received in 2001

Study design
Randomised, controlled study with three parallel groups with balanced allocation (1:1:1).

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Vaccine/immunisation

Interventions

Two doses of GSK Biologicals oral live attenuated human rotavirus (HRV) vaccine (RIX4414) at 106.5 CCID50 viral concentration, one dose of placebo
Control: three doses of placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Live attenuated human rotavirus vaccine (RIX4414), oral poliovirus vaccine

Primary outcome measure
Seroprotection for each polio serotype:
1. Proportion of subjects with anti-poliovirus type 1 antibody titre greater than or equal to 1:8 one month after the third dose
2. Proportion of subjects with anti-poliovirus type 2 antibody titre greater than or equal to 1:8 one month after the third dose
3. Proportion of subjects with anti-poliovirus type 3 antibody titre greater than or equal to 1:8 one month after the third dose

Secondary outcome measures
1. Proportion of subjects with vaccine take one month after each dose of study vaccine at visits 2 and 3 for subset before RV season
2. Proportion of subjects with vaccine take one month after each dose of study vaccine at visits 3 and 4 for subset after RV season*
3. Viral shedding in a subset of subjects
4. Presence of rotavirus in diarrhoeal stools collected between visits 1 and 3 for subset before RV season, and between visits 1 and 4 for subset after RV season
5. Antibody titres for anti-poliovirus type 1, anti-poliovirus type 2, anti-poliovirus type 3 one month after the third dose
6. Serum anti-rotavirus IgA (immunoglobulin A) antibody titres in subjects in the subset before RV season at study visits 1 to 3
7. Serum anti-rotavirus IgA antibody titres in subjects in the subset after RV season at study visits 2 to 4
8. For each type of solicited symptom, occurrence of the symptom within the 15-day (day 0-14) solicited follow-up period after each study vaccine dose
9. Occurrence of unsolicited adverse events within 43 (day 042) days after each study vaccine dose, according to World Health Organization (WHO) classification
10. Occurrence of serious adverse events (SAEs) throughout the entire study period (including long term follow-up for 6 months after Dose 2 of HRV vaccine/placebo)

*Not done since no stool samples were collected after RV season

Overall study start date
01/01/2001

Completion date
01/01/2003

Eligibility

Key inclusion criteria
1. Parents/guardians of subjects who could comply with the protocol requirements (e.g. completion of diary cards, return for follow-up visits)
2. Male or female 6 - 10 weeks of age at the time of first vaccination
3. Written informed consent from parents/guardians
4. Born after a gestation period of 36 - 42 weeks

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Weeks

Upper age limit
10 Weeks

Sex
Both

Target number of participants
271

Key exclusion criteria
1. Use of any investigational or non-registered drug or vaccine other than the study vaccines within 30 days preceding the first dose of study vaccine, or planned use during the study period
2. Previous routine vaccination except Bacillus Calmette-Guerin (BCG) and hepatits B virus (HBV)
3. Clinically significant history of chronic Gastrointestinal Tract (GIT) disease including any incorrected congenital malformation of GIT
4. History of allergic disease or reaction likely to be exacerbated by any component of the vaccine
5. Acute illness at the time of enrolment
6. Diarrhoea with in 7 days preceding the study vaccination
7. Administration of immunoglobulins and/or blood products since birth or planned during study period
8. Use of any investigational or non-registered drug or vaccine other than study vaccines during the study period

Date of first enrolment
01/01/2001

Date of final enrolment
01/01/2003

Locations

Countries of recruitment
South Africa

Switzerland

Study participating centre
20, Avenue Appia
Geneva-27
Switzerland
CH 1211

Sponsor information

Organisation
World Health Organization (WHO)/Department of Immunisation, Vaccines and Biologicals (IVB) (Switzerland)

Sponsor details
20, Avenue Appia
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CH 1211

Sponsor type
Research organisation

Website
http://www.who.int

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
RAPID trials (USA)

Funder Name
World Health Organization (WHO) (Switzerland)

Alternative Name(s)
, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
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