

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	<input type="checkbox"/> Prospectively registered
Registration date 25/11/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/01/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 0-42) 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 hepatitis B virus (HBV)
3. Clinically significant history of chronic Gastrointestinal Tract (GIT) disease including any uncorrected 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 within 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

Geneva -27

Switzerland

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