

A double blind, randomised placebo controlled study of the safety, reactogenicity and immunogenicity of two doses of orally administered human rotavirus vaccine (RIX4414) in healthy infants in South Africa

Submission date 25/11/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 25/11/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 28/01/2008	Condition category Infections and Infestations	☐ 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

Protocol serial number

RPC103

Study information

Scientific Title

Acronym

Rota013

Study objectives

The aim of this study was to determine if there was a difference in immune response between the two different schedules that were tested.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved prior to 2002

Primary study design

Interventional

Study design

A double blind, randomised placebo controlled study

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Vaccine/immunization

Interventions

Two doses of GSK Biologicals oral live attenuated human rotavirus (HRV) vaccine (RIX4414) at 106.5 CCID50 viral concentration

Control: placebo

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Human rotavirus vaccine (RIX4414)

Primary outcome(s)

Proportion of subjects who seroconverted at visit 4 (2 months after dose 3) in the vaccine groups.

Key secondary outcome(s)

Immunogenicity:

1. Proportion of subjects with vaccine take at visit 2 (dose 2) and visit 4 in a subset of subjects
2. Serum rotavirus IgA (immunoglobulin A) antibody concentrations in all subjects at visits 1, 2

and 4

3. Proportion of subjects with anti-poliovirus type 1, 2 and 3 antibody titre greater than or equal to 1:8, at visit 4
4. Antibody titres for anti-poliovirus types 1, 2 and 3, at visit 4
5. Viral shedding in a subset of subjects

Safety:

1. For each type of solicited symptom, occurrence of the symptom within the 15-day (day 0-14) solicited follow-up period after each dose
2. Occurrence of unsolicited adverse events within 43 days (day 0 - 42) after each dose, according to MedDRA (medical dictionary for adverse events) classification
3. Presence of rotavirus in diarrhoeal stool collected until visit 4
4. Occurrence of serious adverse events throughout the entire study period

Efficacy:

1. Occurrence of rotavirus gastroenteritis/severe rotavirus gastroenteritis during the period starting from dose 1 up to visit 5
2. Occurrence of severe rotavirus gastroenteritis during the entire study period

Completion date

25/10/2004

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Weeks

Upper age limit

10 Weeks

Sex

All

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

01/01/2002

Date of final enrolment

25/10/2004

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)

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

Government organisation

Funding Body Subtype

International organizations

Location

Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary