

A phase II, double-blind, randomised, placebo-controlled study to assess the safety, reactogenicity and immunogenicity of three doses of GlaxoSmithKline (GSK) Biologicals oral live attenuated human rotavirus (HRV) vaccine (RIX4414 at 106.5 CCID50) administered to human immunodeficiency virus (HIV) infected infants at 6, 10 and 14 weeks of age 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

01/03/2019

Condition category

Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00263666

Protocol serial number

444563-022

Study information

Scientific Title

A phase II, double-blind, randomised, placebo-controlled study to assess the safety, reactogenicity and immunogenicity of three doses of GlaxoSmithKline (GSK) Biologicals oral live attenuated human rotavirus (HRV) vaccine (RIX4414 at 106.5 CCID50) administered to human immunodeficiency virus (HIV) infected infants at 6, 10 and 14 weeks of age in South Africa

Acronym

Rota022

Study objectives

The aim of this study is to evaluate the reactogenicity, safety and immunogenicity of GSK Biologicals' HRV vaccine given concomitantly with routine vaccines including Oral Poliomyelitis Vaccine (OPV) in HIV positive infants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received in 2004.

Primary study design

Interventional

Study design

Phase II double-blind randomised placebo-controlled study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Vaccine/immunisation

Interventions

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

Control: placebo

Intervention Type

Biological/Vaccine

Phase

Phase II

Primary outcome(s)

Percentage of subjects who report grade "2" or grade "3" fever, vomiting or diarrhoea during the 15-day f/u period after each dose.

Key secondary outcome(s)

1. Reactogenicity
2. Serious adverse events (SAEs)
3. CD4 count and human immunodeficiency virus (HIV) viral load at screening and visit 4
4. Immunogenicity
5. Rotavirus shedding until ceases
6. Enteric pathogens
7. Immunogenicity of antigens contained in concomitantly administered routine vaccine DTPw-HBV/Hib + OPV

Completion date

01/01/2006

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. Documented HIV status of the subject as confirmed by Polymerase Chain Reaction (PCR)
5. HIV asymptomatic and HIV mildly symptomatic
6. Categories N and A according to CDC HIV clinical classification
7. 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. Diarrhea 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

01/01/2004

Date of final enrolment

01/01/2006

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/01/2006		Yes	No
Basic results				No	No