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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

Registration date
25/11/2005

Last Edited
01/03/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00263666

Secondary identifying numbers
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.

Study design
Phase II double-blind randomised placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/01/2004

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

Age group
Child

Lower age limit
6 Weeks

Upper age limit
10 Weeks

Sex
Both

Target number of participants
100

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 enrolement
6. Diarrhea 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
01/01/2004

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)

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

Study outputs

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