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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/11/2005	**Overall study status** Completed	
Last Edited 28/01/2008	**Condition category** Infections and Infestations	

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
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

Study design
A double blind, randomised placebo controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/01/2002

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

Age group

Child

Lower age limit
6 Weeks

Upper age limit
10 Weeks

Sex
Both

Target number of participants
285

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. 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
01/01/2002

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)

Sponsor details
20, Avenue Appia
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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