ISRCTN57452882 https://doi.org/10.1186/ISRCTN57452882

A double-blind randomised placebo controlled dose escalating phase Ib/IIa study to evaluate the safety and immunogenicity of live attenuated rotavirus vaccine 116E in healthy non-malnourished infants eight to 20 weeks of age

Submission date
11/07/2006

Recruitment status
No longer recruiting

Registration date
26/07/2006

Overall study status
Completed

Last Edited
29/09/2009

Condition category
Infections and Infestations

[X] 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
NCT00439660

Secondary identifying numbers
Protocol No. 1

Study information

Scientific Title

Study objectives
Prevention of severe rotavirus diarrhoea in infants by vaccination with the oral rotavirus candidate vaccine 116E, naturally attenuated and reassorted in nature, isolated from an asymptomatic infant.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Independent Ethics Committee and Institutional Review Boards.

Study design
Randomised double blind placebo controlled trial

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
Severe rotavirus diarrhoea

Interventions
Prevention of severe rotavirus diarrhea by vaccination with oral rotavirus candidate vaccine 116E, live attenuated. The control group will receive a placebo vaccine.

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Rotavirus candidate vaccine 116E

Primary outcome measure
Evaluation of the safety of vero cell based 116E rotavirus vaccine candidate strain 116E administered three times orally at four week intervals.

Secondary outcome measures
Evaluation of the immunogenicity of vero cell based 116E rotavirus vaccine candidate strain 116E administered three times orally at four week intervals.

Overall study start date
16/08/2006

Completion date
15/02/2008

Eligibility

Key inclusion criteria
1. Access to a telephone
2. Healthy male and female non-malnourished infants aged six weeks (till six weeks + two days)
3. Parents' permission to participate
4. No plans to travel over the next four months

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Weeks

Upper age limit
6 Weeks

Sex
Both

Target number of participants
540

Key exclusion criteria
1. Gestational age less than 37 weeks
2. Any major physical congenital malformation

3. Contact with immunosuppressed individuals
4. Hospitalised once or more for the following illnesses since birth: heart disease, pneumonia, sepsis, meningitis, unconsciousness
5. Daily medications other than vitamins or herbal "tonics"
6. Evidence of cardiovascular disease
7. Evidence of gastrointestinal disease<br/8. Evidence of neurological disease
9. Evidence of liver or reticuloendothelial disease
10. Evidence of hematologic, rheumatologic or immunologic disease
11. Evidence of renal disease

Date of first enrolment
16/08/2006

Date of final enrolment
15/02/2008

Locations

Countries of recruitment
India

Study participating centre
B-10
New Delhi
India
110 017

Sponsor information

Organisation
Bharat Biotech International Ltd (India)

Sponsor details
Genome Valley
Shameerpet (M)
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500 078
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Sponsor type
Industry

Website

http://www.bharatbiotech.com

ROR
https://ror.org/00rm8g048

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation (BMGF) through Program for Appropriate Technology in Health (PATH) (USA)

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?
Results article	results	01/08/2009		Yes	No