ISRCTN05087777 https://doi.org/10.1186/ISRCTN05087777

Safety and immunogenicity of one and two doses of the live, attenuated oral ETEC candidate vaccine BB01 in healthy adults - a phase I, randomized, double-blind study

Submission date
14/09/2005

Recruitment status
No longer recruiting

Registration date
19/10/2005

Overall study status
Completed

Last Edited
14/02/2008

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Robin McKenzie

Contact details
Center for Immunization Research
Department of International Health
Johns Hopkins University
Bloomberg School of Public Health
Baltimore
United States of America
21205

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Vaccination with an oral live attenuated EnteroToxigenic Escherichia Coli (ETEC) candidate vaccine is safe and well tolerated and immunogenic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised 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
ETEC disease.

Interventions
1. Single dose of ETEC candidate vaccine
2. Two doses of ETEC candidate vaccine

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Vaccine

Primary outcome measure
Safety as measured by the incidence of adverse events reported post-vaccination.

Secondary outcome measures
1. Seroconversion rates as determined by antibody titers pre- and post-vaccination against ETEC candidate vaccine antigens
2. Responder rates as determined by the number of antibody secreting cells pre- and post-vaccination against ETEC candidate vaccine antigens
3. Shedding of ETEC candidate vaccine strain post-vaccination as measured by duration and number of bacteria shedded

Overall study start date
13/05/2005

Completion date
13/01/2006

Eligibility

Key inclusion criteria
Healthy adults between 18 and 45 years of age.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
Any confirmed or suspected immunosuppressive or immunodeficient condition or prior exposure to ETEC.

Date of first enrolment
13/05/2005

Date of final enrolment
13/01/2006

Locations

Countries of recruitment
Switzerland

United States of America

Study participating centre
Center for Immunization Research
Baltimore
United States of America
21205

Sponsor information

Organisation
Berna Biotech Ltd (Switzerland)

Sponsor details
Rehhagstrasse 79A
Bern
Switzerland
3018

Sponsor type
Industry

Website
http://www.bernabiotech.com

Funder(s)

Funder type
Industry

Funder Name
Berna Biotech Ltd (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