

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	<input type="checkbox"/> Prospectively registered
Registration date 19/10/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/02/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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