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Heat-labile toxin (LT) safety study in the elderly

Submission date	Recruitment status	[_] Prospectively registered
29/04/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/05/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/10/2016	Infections and Infestations	[_] Record updated in last year

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
2007-000345-36

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SLA109

Study information

Scientific Title

Phase I open label study to evaluate the safety and immunogenicity of heat-labile toxin (LT) vaccination by transcutaneous immunisation (TCI) in the elderly and compare elderly immune responses with those developed by healthy adults

Study objectives
Enterotoxigenic Escherichia coli (ETEC) is known to be a primary cause of travellers' diarrhoea disease. ETEC organisms contain heat-labile toxin (LT), heat-stable toxin (ST) or both toxins. A vaccine based on LT has the potential to confer protection for subjects exposed to ETEC.

The primary focus of this study is to evaluate the safety of the vaccine in the elderly population (greater than 65 years of age). This study will also compare the anti-heat-labile toxin (anti-LT) immune responses in healthy adults to the immune response in the elderly.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committee in Northern Ireland (ORECNI), 06/03/2007, ref: 07/NIR03 /16

Study design
Parallel randomised controlled open-label single-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Enterotoxigenic Escherichia coli (ETEC) infection

Interventions
Open label, single centre study, enrolling 40 eligible subjects into either group 1 or group 2 in a 1:1 ratio to receive two treatments by transcutaneous immunisation, 21 days apart.

Subjects will receive two doses of LT on a patch via transcutaneous immunisation at days 0 and 21. At the screening visit and on day 42, subjects will have clinical safety laboratory assessments including serum chemistry, haematology, and urinalysis to identify any laboratory abnormalities. On days 7 and 28, elderly subjects will have clinical safety laboratory assessments including serum chemistry, haematology, and urinalysis to identify any laboratory abnormalities. Serum

will be collected at baseline (day 0), and on days 21 and 42 for all study subjects for enzyme-linked immunosorbent assay (ELISA) for anti-LT immunoglobulin G (IgG) and immunoglobulin A (IgA).

Safety will be followed via diary cards and physician review.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Heat-labile toxin (LT) vaccination

Primary outcome measure
To evaluate the safety of two LT vaccinations following skin preparation with the split-path skewed (SPS) buffer in elderly volunteers.

Primary outcome time points: Days 0, 7, 21, 28, 42, 201

Secondary outcome measures
To evaluate the immune responses achieved by two LT vaccinations following skin preparation with the SPS buffer in elderly volunteers and to compare those responses with those of healthy adult volunteers.

Secondary outcome time points: Days 0, 21, 42

Overall study start date
04/04/2007

Completion date
19/02/2008

Eligibility

Key inclusion criteria
1. Healthy elderly (greater than or equal to 65 years of age) or adult (18 - 40 years of age) males and females
2. Signed informed consent
3. Women who are not post-menopausal or surgically sterile must have a negative serum or urine pregnancy test at screening and within 24 hours prior to each vaccination with understanding (through the informed consent process) to not become pregnant through the end of the study. Also, they must agree to employ an effective form of birth control for the duration of the study. Acceptable forms of birth control are: abstinence, hormonal contraceptives (oral, injectable, implant, patch, ring), double-barrier contraceptives (condom, diaphragm with spermicide), and intra-uterine device (IUD)

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Laboratory abnormalities (as determined by the toxicity grading scale [grade 1 - 4]) at laboratory screening
2. Abnormalities at physical examination (as determined by the toxicity grading scale [grade 1 - 4])
3. Known allergies to any component of the vaccine
4. Known disturbance of coagulation
5. Known allergies to adhesives
6. Participated in unrelated research involving investigational product within 90 days before planned date of first vaccination
7. Ever received investigational enterotoxigenic E. coli, LT, or LT (R192G) or NasalFlu, Berna Biotech, Ltd
8. Ever received cholera toxin or vaccine (e.g. Orochol®, Dukoral®)
9. Medical history of acute or chronic skin disease at vaccination site(s)
10. Active skin allergy
11. Recent or regular use of oral or injected steroid medications within 30 days prior to first vaccination
12. Use of immunosuppressive systemic steroid medications including inhaled steroids within three months prior to first vaccination
13. Comorbid conditions or treatments that are immunosuppressive, including cancer, diabetes, end-stage renal disease, as determined by the investigator
14. Positive serology for human immunodeficiency virus-1 (HIV-1), human immunodeficiency virus-2 (HIV-2), hepatitis B surface antigen (HBsAg), or hepatitis C virus (HCV)
15. History of severe atopy
16. Signs or history of acute skin infection, sunburn or skin abnormalities at the vaccination area (s) including fungal infections, severe acne, history of keloid formation, or active contact dermatitis
17. Artificial tanning (ultraviolet [UV] radiation) or use of artificial/spray tan products over the duration of the study including the screening period
18. Hirsute (significant amount of hair) at vaccination area(s)
19. Visible tattoos or marks (tattoos/scars) at the vaccination area(s) that would prevent appropriate dermatological monitoring of the vaccination site(s)
20. Fever equal to or greater than 38.0°C (greater than or equal to 100.4°F) at the time of planned vaccination
21. Suspicion of or recent history of alcohol or substance abuse within one year of planned vaccination
22. Donated blood or blood products such as plasma within the past 90 days
23. Women who are pregnant or breastfeeding
24. Employee of the investigational site
25. Medical history of achlohydria

26. History of abdominal surgery (excluding caesarean section, hysterectomy, cosmetic surgery, liposuction, appendectomy, cholecystectomy, ventral hernia repair, and other surgeries not pertaining to gastrointestinal problems) or history of, or recent, acute gastrointestinal problems

Date of first enrolment
04/04/2007

Date of final enrolment
19/02/2008

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
BioKinetic Europe, Ltd
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BT2 7BA

Sponsor information

Organisation
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Sponsor type
Industry

Website
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ROR
https://ror.org/0144z1077

Funder(s)

Funder type
Industry

Funder Name
Iomai Corporation (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