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A placebo controlled single-blind single-dose study to determine the immunogenicity and safety of freeze dried M01ZH09 typhoid vaccine in healthy adult volunteers from Viet Nam

Submission date
10/11/2006

Recruitment status
No longer recruiting

Registration date
20/11/2006

Overall study status
Completed

Last Edited
05/02/2015

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

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Additional identifiers

Protocol serial number
Oxtrec 005-05; 061330

Study information

Scientific Title
A placebo controlled single-blind single-dose study to determine the immunogenicity and safety of freeze dried M01ZH09 typhoid vaccine in healthy adult volunteers from Viet Nam

Acronym
MS 01.07 study

Study objectives
The clinical studies performed to date with M01ZH09 have assessed safety, tolerability and immunogenicity in subjects in the United States of America (USA) and United Kingdom (UK). Later in the clinical development of M01ZH09, phase III field trials will be necessary in an area where typhoid fever is endemic. Potential endemic areas for such a study exist in Viet Nam. The purpose of this study is to demonstrate safety and immunogenicity in a Vietnamese population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Tropical Research Ethics Committee (OXTREC), 23/03/2005, ref: 005-05

Study design
Placebo-controlled single-blind single-dose study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Typhoid Fever

Interventions
Subjects will receive a single dose of M01ZH09 administered orally. The oral route of administration is the normal route of entry for S. typhi hence it is appropriate to administer the vaccine by the same route.

There will be two groups of subjects: 16 subjects will be randomised to receive a dose of 5 x 10^9 CFU of M01ZH09 oral vaccine and 12 subjects will receive placebo. M01ZH09 is supplied as a freeze-dried formulation of the vaccine strain, plus excipients in single dose vials. The placebo is supplied as a freeze-dried formulation of vaccine excipients only in single dose vials.

In Group one, subjects will receive the M01ZH09 vaccine in 150 mL of a solution containing 1.75% (w/v) sodium bicarbonate, 1.1% (w/v) ascorbic acid and 0.02% (w/v) aspartame. The solution is prepared from the supplied buffer tablets using potable tap water.

In Group two, subjects will receive placebo, consisting of the vaccine excipients in 150 mL of a solution containing 1.75% (w/v) sodium bicarbonate, 1.1% (w/v) ascorbic acid and 0.02% (w/v) aspartame. The solution is prepared from the supplied buffer tablets using potable tap water.

Intervention Type

Biological/Vaccine

Primary outcome(s)
Subjects were considered to have had an immune response if they achieved a day seven result of more than or equal to four Antibody-Secreting Cells (ASCs) per 10^6 Peripheral Blood Mononuclear Cells (PBMC), secreting Immunoglobulin A (IgA) specific for S. typhi LipoPolySaccharide (LPS) detected by Enzyme-Linked Immunosorbent Spot (ELISPOT) assay, (assuming a day zero result of less than four ASCs per 10^6 PBMC), and/or undergo seroconversion for serum Immunoglobulin G (IgG) to LPS.

Seroconversion for serum IgG to LPS is defined as a four-fold or greater increase in the serum IgG antibody on serial dilution by Enzyme- Linked Immunosorbant Assay (ELISA), to S. typhi LPS between day zero and day 28.

Key secondary outcome(s))
No secondary outcome measures

Completion date
28/02/2006

Eligibility

Key inclusion criteria
1. Healthy adult volunteers aged 19 to 30 years inclusive of Vietnamese origin, who are able and willing to give written informed consent, following a detailed explanation of participation in the study
2. Volunteers who will be available for the duration of the study and available for scheduled and potential additional visits

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Any clinically significant medical or psychiatric condition or clinically significant abnormal serum biochemistry or haematology results that, in opinion of the Investigator, preclude participation in the study
2. Female subjects who are pregnant (confirmed with urinary pregnancy test) or breastfeeding, or of childbearing potential and unwilling to use a reliable method of contraception (oral contraceptives or barrier method with spermicidal preparation) throughout the study period
3. Have known hypersensitivity to ciprofloxacin and trimethoprim sulphamethoxazole or used antibiotics/antibacterials within 14 days prior to administration of study medication

4. Have known hypersensitivity to any component of the vaccine or buffer solution used in this study, including subjects with phenylketonuria or have experience anaphylactic shock after vaccination
5. Have received any vaccine against S. typhi whether licensed or investigational, in the last ten years, or who have ever suffered from typhoid fever
6. Work as commercial food handlers
7. Direct contact with groups at risk of infections (e.g. patients in special care units, immuno-compromised individuals, pregnant women, children less than two years of age and individuals more than 70 years)
8. Have a positive bacterial culture of their faecal sample obtained at the screening visit, for any Salmonella species
9. A known impairment of immune function including Acquired Immune Deficiency Syndrome (AIDS) or those receiving (or have received in the six months prior to study entry) cytotoxic drugs immunosuppressive therapy (including systemic corticosteroids) or have an Immunoglobulin A (IgA) deficiency
10. Human Immunodeficiency Virus (HIV), Hepatitis B or Hepatitis C positive
11. A significant acute febrile illness (fever of 38.0°C or more) at time of dosing
12. Chronic diseases: this will include all autoimmune and immuno-compromising conditions and any other chronic condition, which at the judgement of the investigator, may put the subject at higher risk of side effects from the study vaccine. Conditions in the latter category might include:
a. unexplained anaemia
b. hepato-biliary disease
c. uncontrolled hypertension
d. subjects with prosthetic joints or heart valves, etc.,
13. A current problem, based on history, with substance abuse or with a history of substance abuse that, in the opinion of the investigator, might interfere with participation in the study including inability to refrain from smoking for 48 hours
14. Are currently involved in a clinical study, have taken an investigational drug or have received investigational or licensed vaccines in the preceding four weeks from screening or anticipate receiving a vaccine other than study medication during the first four weeks, post vaccination, of the study
15. A known or suspected history of liver or active gall bladder disease
16. Use antacids, proton pump inhibitors or H2 blockers on a regular basis or have consumed proton pump inhibitors or H2 blockers within 24 hours prior to dosing
17. Subjects excluded for medical reasons will be referred to appropriate medical care services or counselling

Date of first enrolment
18/10/2005

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Viet Nam

Study participating centre

The Hospital for Tropical Diseases
Ho Chi Minh City
Viet Nam
District 5

Sponsor information

Organisation
Emergent Europe Ltd (UK)

ROR
https://ror.org/007nce146

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration