

A placebo controlled, single-blind, single oral dose study to determine the safety and immunogenicity of M01ZH09 typhoid vaccine (oral live *S. typhi* [Ty2 aroC- ssaV-] ZH9) in healthy paediatric subjects, aged five to 14 years inclusive, of Vietnamese origin

Submission date 17/01/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 07/02/2007	Overall study status Completed	☐ Protocol
Last Edited 13/03/2013	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ 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

Protocol serial number

Study information

Scientific Title

Acronym

MS01.08

Study objectives

The purpose of the study is to determine the safety and immunogenicity of the oral vaccine M01ZH09 in healthy, paediatric, Asian subjects prior to initiating field trials in an endemic area.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The trial has received full ethical approval from the OXTREC committee (ref: 021-06) and the local Institutional Review Board (The Hospital for Tropical Diseases, Ho Chi Minh City, Viet Nam). The approval dates are 25th July 2006, for conditional approval, and final unconditional approval was received on the 18th October 2006.

Primary study design

Interventional

Study design

Randomised, placebo-controlled, single-blind, single dose study.

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Typhoid fever prophylaxis

Interventions

Subjects deemed eligible after screening will be randomised to receive an oral dose of either active vaccine or matching placebo.

Safety will be monitored by:

1. Diary recordings of body temperature
2. Assessment of Adverse Events (AEs)
3. Vital signs
4. Stool samples for microbiological analyses
5. Urine dipstick tests
6. Immunogenicity will be assessed in all subjects using an Enzyme-Linked ImmunoSorbent Assay (ELISA) method for serum Immunoglobulin G (IgG) and serum Immunoglobulin A (IgA) in all subjects. Enzyme-Linked Immunosorbent SPOT (ELISPOT) tests will be conducted on samples from subjects aged 11 to 14 years of age.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

M01ZH09 typhoid vaccine (oral live *S. typhi* [Ty2 aroC- ssaV-] ZH9)

Primary outcome(s)

The proportion of subjects reporting Serious Adverse Events (SAEs) attributed to the study medication.

Key secondary outcome(s)

Safety - the proportion of subjects:

1. Experiencing an elevated body temperature, of 38.5°C or greater, in the 14 days following dosing, attributed to study medication
2. Demonstrating persistent faecal shedding of the vaccine strain
3. Withdrawn from the study due to adverse events, including bacteraemia, attributed to study medication
4. With clinically significant changes in laboratory parameters, from day zero to any time post dosing, which are attributed to study medication

Immunogenicity:

1. Develop a positive immune response to *S. typhi* LipoPolySaccharide (LPS) as assessed by an increase in *S. typhi* LPS specific IgG
2. Develop a positive immune response to *S. typhi* LPS as assessed by an increase *S. typhi* LPS specific IgA
3. At day seven, have more than or equal to 4 Antibody-Secreting Cells (ASCs) per 10⁶ Peripheral Blood Mononuclear Cells (PBMC), secreting IgA specific for *S. typhi* LPS detected by ELISPOT assay (subjects over ten years of age)

Completion date

31/05/2007

Eligibility**Key inclusion criteria**

1. Healthy paediatric subjects aged five to 14 years
2. Are able and willing to take part in the trial
3. Parents or guardians give written permission for their child's participation, following a detailed explanation of the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 Years

Upper age limit

14 Years

Sex

Not Specified

Key exclusion criteria

1. Any clinically significant medical or psychiatric condition or abnormal laboratory results on screening, which preclude participation in the study
2. A body weight under 17 kg (five to ten year olds), or under 27 kg (11 to 14 year olds)
3. A confirmed pregnancy, or are breast feeding
4. A known hypersensitivity to two or more of the following antibiotics: ciprofloxacin, azithromycin or trimethoprim-sulfamethoxazole, or have used antibiotics/antibacterials within 14 days prior to administration of study medication
5. A known hypersensitivity to any component of the vaccine or bicarbonate solution, phenylketonuria or those who have experienced anaphylactic shock after any vaccination
6. Received Vivotif, in the last ten years or any other vaccine against *S. typhi*, in the last five years, or who have ever suffered from typhoid fever
7. Direct contact with patients in special care units or immuno-compromised individuals, a positive bacterial culture of their faecal sample, obtained at the screening visit, for any *Salmonella* species, a known impairment of immune function or family members who are Human Immunodeficiency Virus (HIV) positive
8. A significant acute febrile illness at time of dosing chronic diseases, a current problem of substance abuse or who are currently or recently involved in a clinical study

Date of first enrolment

26/01/2007

Date of final enrolment

31/05/2007

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 Product Development UK Ltd (UK)

ROR

<https://ror.org/007nce146>

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 075596)

Results and Publications

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	26/07/2010		Yes	No