ISRCTN91111837 https://doi.org/10.1186/ISRCTN91111837

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

Registration date
07/02/2007

Overall study status
Completed

Last Edited
13/03/2013

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Jeremy Farrar

Contact details
The Hospital for Tropical Diseases
Oxford University Clinical Research Unit
190 Ben Ham Tu
Ho Chi Minh City
Viet Nam
District 5
+84 (0)8 923 7954
jfarrar@oucru.org

Additional identifiers

Protocol serial number

075596

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.

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

Primary study design
Interventional

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 10^6 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 childs 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