

Comparison of immune responses elicited by oral and parenteral typhoid fever vaccines

Submission date 17/06/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 06/11/2013	Condition category Infections and Infestations	<input type="checkbox"/> 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
Ty21a - ASC

Study information

Scientific Title

Comparison of immune responses elicited by oral and parenteral typhoid fever vaccines: a randomised controlled single centre study

Study objectives

Evaluation of the immune response as elicited by the oral Ty21a typhoid fever vaccine or a parenteral Vi-capsular polysaccharide vaccine using different immunological methods.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Internal Medicine, Helsinki University Central Hospital, approved on the 8th April 2009. Amendment approved on the 4th September 2009.

Study design

Randomised controlled single centre study

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Prophylaxis of typhoid fever

Interventions

Biological:

Group A: Three oral doses of Vivotif®; administered with an interval of 1 day

Group B: one intramuscular dose of Typherix®; will be administered

Total duration of follow-up: approximately four weeks

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Vivotif®, Typherix®

Primary outcome(s)

Measurement of specific IgA- IgG- and IgM-secreting antibody cells in peripheral blood using ELISPOT, measured at day 7.

Key secondary outcome(s)

1. To evaluate the expression of various homing receptors on antigen-specific antibody-secreting cells by separating the PBMCs with immunomagnetic cell sorting according to their HR expressions and by investigating specific ASC in the resulting subpopulations

2. Antibody analyses from serum (Widal test/ELISA)
3. Cell-mediated immune response

Measured at week 1 and 4.

Completion date

30/06/2011

Eligibility

Key inclusion criteria

1. Male or female subjects aged 18 to 65 years
2. Free of obvious health problems
3. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Vaccination against typhoid fever within 5 years before dosing
2. History of clinical typhoid fever, clinical paratyphoid A or B fever
3. Current intake of antibiotics or end of antibiotic therapy less than 8 days before first investigative medicinal product (IMP) administration
4. Standard exclusion criteria (allergic to vaccine components, acute disease, immunosuppressed, serious chronic illness, pregnancy or lactation, etc.)

Date of first enrolment

01/08/2010

Date of final enrolment

30/06/2011

Locations

Countries of recruitment

Finland

Study participating centre
Helsinki University Central Hospital
Helsinki
Finland
00029

Sponsor information

Organisation

Helsinki University Central Hospital (Finland)

ROR

<https://ror.org/02e8hzf44>

Funder(s)

Funder type

Industry

Funder Name

Crucell Switzerland AG (Switzerland)

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	26/11/2012		Yes	No
Results article	results	08/04/2013		Yes	No