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

Submission date	Recruitment status	[X] Prospectively registered
17/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/07/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/11/2013	Infections and Infestations	

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.

Primary study design
Interventional

Study design
Randomised controlled single centre study

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, pregancy 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