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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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.

Overall study start date
01/08/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

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)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Industry

Funder Name
Crucell Switzerland AG (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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