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Nutrition effects on oral vaccination

Submission date	Recruitment status	[ ] Prospectively registered
24/02/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/02/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/02/2009	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
067948; Well07

Study information

Scientific Title

Oral vaccination: effects on non-specific host defence in the intestine and the interaction with micronutrients

Acronym
OVN

Study objectives
That live, attenuated oral vaccines up-regulate innate immune responses in the intestine, which would be expected to give non-specific protection against other diarrhoea pathogens, and that micronutrients can enhance the innate immune response to oral vaccines.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Zambia School of Medicine Research Ethics Committee gave approval on the 3rd December 2007

Study design
Two phase study: initial observational study followed by randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Mucosal immunology and nutrition

Interventions
Phase 1a: Rotarix® oral rotavirus vaccine - 1 dose
Phase 1b: Vivotif® oral typhoid vaccine - 1, 2, or 3 doses at intervals of 48 hours

Phase 2: the vaccine chosen and the number of doses will depend on results of phase 2b which are not yet fully analysed. The dose of the micronutrient supplement used (the randomised element) will be 2 tablets of Immunace® (which includes 23 micronutrients) daily, or placebo, for 2 months. Immunace is made by Vitabiotics Plc.

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Rotarix®, Vivotif®

Primary outcome measure
Expression of antimicrobial peptides and cytokines in micronutrient recipients compared to placebo.

Enteroscopy will be carried out on day 0 (the day of immunisation), which will be after the participant has been receiving the micronutrient supplement or placebo for 2 months) and then again at one specific time point after that (undecided as of 25/02/2009). The purpose of enteroscopy is to obtain seven biopsies from the jejunum which will be processed for analysis of messenger ribonucleic acid (mRNA), antimicrobial peptides and cytokines by real time polymerase chain reaction (RT-PCR).

Secondary outcome measures
Response of peripheral blood mononuclear cells to vaccine antigens in vitro in micronutrient recipients compared to placebo.

Blood will be collected on the same day as the the enteroscopy and peripheral blood mononuclear cells (PBMCs) prepared by Ficoll centrifugation. An assay of mRNA will be by RT-PCR.

Overall study start date
01/01/2008

Completion date
31/10/2009

Eligibility

Key inclusion criteria
1. Residence in ongoing cohort study area in Misisi township, Lusaka
2. Aged greater than 18 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Helminth infection
2. Pregnancy
3. Breastfeeding
4. Aged greater than 65 years
5. Diarrhoea within one month prior to recruitment
6. Medication with antibiotics or non-steroidal anti-inflammatory drugs (NSAIDs) within one month prior to recruitment
7. Any vaccination within 6 months prior to recruitment

Date of first enrolment
01/01/2008

Date of final enrolment
31/10/2009

Locations

Countries of recruitment
England

United Kingdom

Zambia

Study participating centre
Institute of Cell and Molecular Science
London
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Sponsor information

Organisation
Queen Mary University of London (UK)

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Sponsor type
University/education

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ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 067948)

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