

# Nutrition effects on oral vaccination

<b>Submission date</b> 24/02/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/02/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/02/2009	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Paul Kelly

**Contact details**  
Institute of Cell and Molecular Science  
Barts & The London School of Medicine  
London  
United Kingdom  
E1 2AD  
+44 (0)20 7882 2643  
m.p.kelly@qmul.ac.uk

## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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).

### **Key secondary outcome(s)**

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.

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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

United Kingdom

England

Zambia

### Study participating centre

Institute of Cell and Molecular Science

London

United Kingdom

E1 2AD

## Sponsor information

### Organisation

Queen Mary University of London (UK)

### ROR

<https://ror.org/026zzn846>

## Funder(s)

### Funder type

Charity

### Funder Name

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

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration