

Nutrition effects on oral vaccination

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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