

The impact of micronutrient supplementation on the health of Zambian adults with particular emphasis on intestinal infection

Submission date 22/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/07/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/09/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
067948

Study information

Scientific Title

Integrity of small intestinal antimicrobial defence in relation to micronutrients in Zambian adults

Study objectives

To determine if a multiple micronutrient supplement boosts intestinal innate immunity in adults living in an urban environment in Africa.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Obtained from two ethics committees:

1. University of Zambia Research Ethics Committee
2. London School of Hygiene and Tropical Medicine Research Ethics Committee

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Intestinal innate immunity

Interventions

Randomised, placebo-controlled trial of solid tablet formulation of 15 micronutrients, administered daily, with cross-over after two years.

The anticipated end date of this trial has been shortened to 1st January 2007, the previous anticipated end date was 31/08/2007.

Intervention Type

Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Multiple micronutrient supplement

Primary outcome(s)

1. Frequency of diarrhoeal disease
2. CD4 count in human immunodeficiency virus (HIV) seropositive participants
3. Expression of antimicrobial peptides in small intestinal tissue and secretions
4. Change in micronutrient status

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/01/2007

Eligibility

Key inclusion criteria

All adults (over 18 years of age, either sex) resident within a defined geographical area of Misisi compound, Lusaka, Zambia, have been invited to participate.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/06/2003

Date of final enrolment

01/01/2007

Locations

Countries of recruitment

Zambia

Study participating centre

Tropical Gastroenterology & Nutrition Group

Lusaka

Zambia

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Sponsor information

Organisation

London School of Hygiene and Tropical Medicine (UK)

ROR

<https://ror.org/00a0jsq62>

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2008		Yes	No
Results article	results	06/07/2010		Yes	No
Results article	results	25/03/2014		Yes	No