

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

☐ Prospectively registered

☐ Protocol

Registration date
22/07/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
15/09/2014

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/06/2003

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

500

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)

Sponsor details

Research Grants and Contracts Office

Keppel Street

London

England

United Kingdom

WC1E 7HT

+44 (0)20 7827 2678

Penny.Ireland@lshtm.ac.uk

Sponsor type

University/education

Website

<http://www.lshtm.ac.uk>

ROR

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

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

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 |