ISRCTN37460449 https://doi.org/10.1186/ISRCTN37460449

Chilenje Infant Growth, Nutrition and Infection Study

Submission date	Recruitment status
28/06/2005	No longer recruiting
Registration date	**Overall study status**
05/08/2005	Completed
Last Edited	**Condition category**
13/01/2015	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Suzanne Filteau

Contact details
Nutrition and Public Health Interventions Research Unit
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Additional identifiers

Study information

Scientific Title
Chilenje Infant Growth, Nutrition and Infection Study

Acronym
CIGNIS

Study objectives

Feeding for 12 months with a fortified complementary food will decrease the proportion of stunted children by 30%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 02/09/10:
1. Approved by the University of Zambia ethics committee
2. Approved by the London School of Hygiene and Tropical Medicine ethics committee

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Infant growth faltering

Interventions
One of two locally developed complementary foods fed for 12 months

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Prevalence of stunting

Key secondary outcome(s)
1. Body composition
2. Indices of iron (Fe), zinc (Zn), copper (Cu), selenium (Se) and vitamin A status
3. Morbidity
4. Gastrointestinal permeability
5. Response to oral polio vaccine
6. Behavioural development
7. Development of chronic childhood viral infections

Completion date
30/06/2008

Eligibility

Key inclusion criteria
Infants aged 6 months and resident in Chilenje, Zambia whose mothers agree:
1. To prepare and feed their infants for 12 months the food supplied to them
2. To attend the specified clinic or home visits
3. To let their infants undergo specified urine collection and blood sampling
4. To permit the infants to be tested for human immunodeficiency virus (HIV)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Months

Sex
All

Key exclusion criteria
Non-fulfilment of inclusion criteria or evidence of chronic disease (active tuberculosis [TB], symptomatic HIV)

Date of first enrolment
20/07/2005

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
United Kingdom

England

Zambia

Study participating centre
Nutrition and Public Health Interventions Research Unit
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
Bill and Melinda Gates Foundation (USA)

ROR
https://ror.org/0456r8d26

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation (USA) - (ref: 37253)

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
DSM (South Africa)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/05/2011	Yes	No
Results article	results	01/02/2012	Yes	No
Results article	results	01/03/2012	Yes	No
Results article	results	01/11/2014	Yes	No