

Chilenje Infant Growth, Nutrition and Infection Study

Submission date 28/06/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/08/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/01/2015	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
N/A

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

Study design

Randomised controlled trial

Primary study design

Interventional

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?
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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