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The effect of feeding weaning foods that contain moringa leaf powder on growth and haemoglobin levels of Ghanian infants aged 8-12 months

Submission date
23/04/2015

Recruitment status
No longer recruiting

Registration date
12/05/2015

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
When infants aged 6-24 months from low-income countries start eating a wide range of foods in addition to breast milk (weaning), they often develop a number of nutritional and health problems. This is because the food they are eating is low in essential nutrients, which may result in poor growth and development, and an increase in common childhood illnesses such as diarrhoea. The typical diet for weaning in such countries is made up of starchy foods, such as a cereal (maize, rice) or tuber vegetables (cassava, yams). There are limited amounts of fruits, vegetables, legumes, and pulses available and very little meat or dairy foods. Moringa oleifera, an edible tree commonly found in dry tropical regions, has been shown to be a valuable source of nutrients, including protein, calcium, iron, vitamin C, and vitamin A. The moringa leaf can be made into a powder to be combined with flour or used as 'sprinkles' to mix with other food. As a result, it is used more and more as a food supplement in developing countries where poor nutrition is a major concern. The aim of this study is to see whether moringa leaf powder affects growth and weight gain in weaning infants from Asesewa, Ghana, an area with very high rates of infant malnutrition.

Who can participate?
Carers with weaning infants aged 8-12 months.

What does the study involve?
Participants are randomly allocated into one of three groups. Those in group 1 (intervention group) are given a 35g daily ration of cereal legume flour with added moringa leaf powder. Those in group 2 (intervention group) are given a 5g daily ration of moringa leaf powder. Those in group 3 (control group) are given a 35g daily ration of cereal legume flour without moringa leaf powder. All participants are given nutrition education by a trained researcher. Questionnaires and interviews are used at the start of the study to assess home life and health

history of participating infants and carers. All infants' have weight and height measurements and a finger prick blood test at the start and end of the study. Families are visited by a researcher every 2 weeks for four months.

What are the possible benefits and risks of participating?
The results of this study will be very useful in informing recommendations for improving the quality of foods fed to infants after the first 6 months of life when weaning foods are introduced. Infants will receive study foods free of charge as well as nutrition education on how to feed infants hygienically. There are no foreseeable risks to participation in this study. The finger prick test may bring temporary discomfort to infants, but it is carried out by a qualified and trained researcher.

Where is the study run from?
University of Ghana Nutrition Research and Training Centre (Ghana)

When is the study starting and how long is it expected to run for?
September 2014 to November 2015

Who is funding the study?
International Development Research Centre (Canada)

Who is the main contact?
Mrs L Boateng

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

GHS-ERC 07/09/14

Study information

Scientific Title
Effect of complementary foods that incorporate moringa leaf powder, on growth and micronutrient status of Ghanian infants from age 8-12 months: a randomised controlled trial

Study objectives
Infants fed moringa leaf powder either as part of cereal-legume blended flour or as a food supplement for 4 months will have significantly higher weight and length gain, haemoglobin levels and vitamin A levels, than infants fed the cereal-legume blended flour without moringa.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Noguchi Memorial Institute for Medical Research - Institutional Review Board, 17/07/2014, ref: NMIMR –IRB CPN -106/14-14.
2. Ghana Health Service - Ethics Review Committee, 22/11/2014, ref: GHS-ERC: 07/09/14.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Protein-energy malnutrition and micro-nutrient malnutrition.

Interventions
1. Group 1 (treatment): 35g daily ration of cereal legume flour with moringa leaf powder plus nutrition education.
2. Group 2 (treatment): 5g daily ration of moringa leaf powder plus nutrition education.
3. Group 3 (control): 35g daily ration of cereal legume flour without moringa leaf powder plus nutrition education.

Intervention Type
Supplement

Primary outcome measure
Haemoglobin levels after 4 months of daily feeding

Secondary outcome measures
Growth after 4 months of daily feeding

Overall study start date
09/09/2015

Completion date
30/11/2015

Eligibility

Key inclusion criteria
1. Infants aged between 8-12 months
2. Infant is breastfed
3. Caregiver of infant is willing to stay in the study area for the next 4 months
4. Infant tolerates ingredients in the study foods (maize, soya bean, dark green leafy vegetables).

Participant type(s)
Carer

Age group
Child

Lower age limit
8 Months

Upper age limit
12 Months

Sex
Both

Target number of participants
Sample size calculation was based on the detection of differences among the 3 intervention groups equivalent to a “medium” effect size [Cohen’s d = (difference/pooled SD) = 0.5] (Cohen, 1988). With a type I error of 0.05 and a 0.8 probability of detecting a true difference (1- β), the required sample size per group was 77. Allowing for 15% attrition in the 3 intervention groups, the target sample size for each group was 91. A employed a community based randomisation approach was employed in assigning of infants to the 3 study arms. Thus it was important to account for the design effect by multiplying our sample size by a factor of 1.5 giving a total of 137 infants in each study arm, giving a total of 411 study participants

Key exclusion criteria

1. Infant below 8 months or older than 12 months
2. Infant not breastfed
3. Caregiver of infant is unwilling to stay in the study area for the next 4 months
4. Infant is unable to tolerate ingredients in the study foods (maize, soya bean, dark green leafy vegetables).

Date of first enrolment
10/12/2014

Date of final enrolment
31/07/2015

Locations

Countries of recruitment
Ghana

Study participating centre
University of Ghana Nutrition Research and Training Centre
Asesewa
Ghana
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Sponsor information

Organisation
International Development Research Centre

Sponsor details
150 Kent Street
Ottawa, ON
Canada K1P 0B2
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Sponsor type
Research organisation

Organisation
University of Ghana

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Sponsor type
University/education

Funder(s)

Funder type
Government

Funder Name
International Development Research Centre

Alternative Name(s)
Centre de recherches pour le développement international, IDRC, CRDI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

Results and Publications

Publication and dissemination plan
Findings of the study will be presented at the Department of Nutrition and Food Science, University of Ghana. I will also present preliminary results at the National Health Research Symposium in Ghana in May, 2015. Findings will also be presented at the FAO headquarters in Rome. FAO is very much interested in using food-based approaches to improve dietary intakes thus the results of this study will be of immense interest and may be beneficial in shaping policy on infant feeding. At least 3 manuscripts on the work will be submitted to a professional journals starting from January, 2015.

Intention to publish date
01/06/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/06/2018	17/12/2020	Yes	No
Results article		20/11/2018	14/06/2023	Yes	No