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The WinFood Intervention Study: the effect of improved complementary foods on nutrition and health among infants in Western Kenya

Submission date
30/03/2012

Recruitment status
No longer recruiting

Registration date
11/05/2012

Overall study status
Completed

Last Edited
17/02/2023

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:
The World Health Organization recommends that infants be exclusively breastfed with no other food or liquid given until the age of 6 months. At 6 months, other foods need to be introduced to complement breast milk. In developing countries, including Kenya, such foods introduced at the age of 6 months or earlier mainly comprise thin porridges made exclusively from plant based foodstuffs. It is likely that the sharp growth faltering observed from 6 months onto 2 years and beyond is associated with consumption of foods that provide inadequate energy and sub-optimal amounts of essential nutrients such as iron and zinc. The Winfood Project is a collaboration between University of Copenhagen and University of Nairobi aiming to improve the quality of complementary foods fed to infants and young children in Kenya so as to improve growth and health via utilisation of often neglected traditional foodstuffs such as small fish, edible insects and grains and processing them in a way that nutrient and energy density is enhanced.
The trial aims to test the effect of three foods:
Winfood Classic with maize, grain amaranth, edible termites and fish
Winfood Lite maize, grain amaranth and premix of vitamins and minerals
Corn soy blend plus (CSB+) with mineral and vitamin premix
The effect on growth, lean and body fat composition, gross psychomotor milestones, zinc and iron status of Kenyan infants and young children supplemented for 9 months from 6-15 months of age will be measured.

Who can participate?
Normal infants living in rural Western Kenya - all non-malnourished, non-severely anaemic 6-month old infants. In total 500 infants will take part for 9 months.

What does the study involve?
Six-month old infants are randomly allocated to one of the three study foods, listed above. In order to monitor growth, weight, length, head circumference, and mid upper arm circumferences are measured monthly. Haemoglobin, is measured by finger prick and venous blood is drawn to measure iron and zinc status at 6 months and 15 months of age. In order to

determine lean mass and body fat composition in the infants, saliva samples are drawn and analysed.

What are the possible benefits and risks of participating?
The benefits include receiving food rations for 9 months. Additionally, we expect improved growth and health among infants receiving food supplementation. There may be discomfort to children due to pain during drawing of blood. Otherwise there are no direct risks that may be associated with this study.

Where is the study run from?
This study is based in three rural health centres in Mumias District, Western Province, Kenya.

When is study starting and how long is it expected to run for?
The study commenced in January 2012 and is expected to run until January 2013.

Who is funding the study?
Danish International Development Agency (DANIDA)

Who is the main contact?
Prof Henrik Friis
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Contact information

Type(s)
Scientific

Contact name
Prof Henrik Friis

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University of Copenhagen
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The WinFood Intervention Study: randomised controlled trial of the effect of improved complementary foods on infant growth, body composition and gross motor development in Western Kenya

Acronym
WinFood

Study objectives
Improved complementary foods based on locally available traditional ingredients will improve the nutritional and health status of Kenyan infants

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kenyatta National Hospital and University of Nairobi Ethics Committee, Kenya 07 April 2011

Study design
Randomised double-blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Infants at risk of undernutrition

Interventions
Three different pre-cooked complementary food supplements given as a porridge daily from 6-15 months of age (6-8 months: 50 g, 9-12 months: 75 g, 13-15 months: 125 g)
1. WinFood CF: amaranth grain, maize and one highly-nutritious fish and one edible termite species
2. WinFood Light: amaranth grain, maize plus vitamin-mineral premix
3. Corn-Soy-Blend Plus (CSB+)

Food class (1 & 2) are the experimental and food class (3) is the control intervention

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Changes in linear growth (stunting), fat-free body mass (deuterium dilution), iron status (serum ferritin and transferrin receptors) from baseline (age 6 months) until the end of the 9 month intervention

Secondary outcome measures
Changes in:
1. Physical activity (using an accelerometer, actigraph)
2. Motor milestones (questionnaire, clinic visits)
3. Morbidity
4. Haemoglobin concentration (using Haemocue)
5. Serum concentrations of acute phase proteins [C-reactive protein (CRP) and a-acid glycoprotein(AGP)], insulin-like growth factor (IGF)-1 and zinc
6. Whole blood fatty acid composition

Measured from baseline (age 6 months) until the end of the 9 month intervention

Overall study start date
15/01/2012

Completion date
30/12/2012

Eligibility

Key inclusion criteria
Children who are 6 months old and have a weight-for-height z-score > -3

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
450

Total final enrolment
499

Key exclusion criteria
1. Weight-for-height z-score < -3
2. Bilateral pitting oedema
3. Haemoglobin (Hb) < 80 g/L
4. Clinical signs of vitamin A deficiency (xerosis or Bitot spots). These children will be referred for treatment

Date of first enrolment
15/01/2012

Date of final enrolment
30/12/2012

Locations

Countries of recruitment
Denmark

Kenya

Study participating centre
University of Copenhagen
Frederiksberg
Denmark
1958

Sponsor information

Organisation
University of Copenhagen (Denmark)

Sponsor details
Rolighedsvej 30
Frederiksberg
Denmark
1958

Sponsor type
University/education

Website
http://www.ku.dk/english/

ROR
https://ror.org/035b05819

Funder(s)

Funder type
Government

Funder Name
Danish Ministry of Foreign Affairs - Danish International Development Agency (Denmark) ref: 57-08-LIFE

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/10/2019	07/05/2019	Yes	No
Results article		14/02/2023	17/02/2023	Yes	No