

The WinFood Intervention Study: the effects of improved complementary foods on nutrition and health among Cambodian infants and children

Submission date

24/02/2011

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

25/03/2011

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

04/06/2015

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

Prof Henrik Friis

Contact details

Rolighedvej 30

Frederiksberg

Denmark

1958

-

hfr@life.ku.dk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The WinFood Intervention Study: the effects of improved complementary foods on nutrition and health among Cambodian infants and children, a randomised, single-blind study

Acronym

WinFood

Study objectives

Improved complementary foods based on locally available traditional ingredients will improve the nutritional and health status of Cambodian infants and children

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Ethics Committee for Health Research (NECHR), Cambodia, 22/10/2010, ref: Version No 1 dated 28-05-2010

Study design

Randomised single-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

Four 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: rice and two highly-nutritious fish and one spider species
2. WinFood Light: rice and a common fish species plus vitamin-mineral premix
3. Corn-Soy-Blend Plus (CSB+)

4. Corn-Soy-Blend Plus Plus (CSB++).

Food class (1 & 2) are the experimental and food class (3 & 4) are the control interventions

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

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

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

Overall study start date

07/03/2011

Completion date

10/02/2012

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

Child

Lower age limit

6 Months

Sex

Both

Target number of participants

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

07/03/2011

Date of final enrolment

10/02/2012

Locations**Countries of recruitment**

Cambodia

Denmark

Study participating centre

Rolighedvej 30

Frederiksberg

Denmark

1958

Sponsor information**Organisation**

University of Copenhagen (Denmark)

Sponsor details

Department of Human Nutrition

Rolighedsvej 30

Frederiksberg

Denmark

1958

-

hfr@life.ku.dk

Sponsor type

University/education

ROR

<https://ror.org/035b05819>

Funder(s)

Funder type

Government

Funder Name

Danish Ministry of Foreign Affairs (Denmark) - Danish International Development Agency (Danida) (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

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	01/01/2014		Yes	No
Results article	results	01/04/2015		Yes	No