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The Ready to Use Complementary Food (RUCF) Study

Submission date
08/11/2009

Registration date
28/04/2010

Last Edited
19/06/2012

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[_] 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 Paluku Bahwere

Contact details
Fond Tasnier 6
Genval
Belgium
1332

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

The impact of high nutrient dense Ready to Use Complementary Food (RUCF) on growth of children below 2 years in South Kivu, Eastern Democratic Republic of Congo: a randomised controlled interventional trial

Acronym
S-RUCF

Study objectives
This study will test the hypothesis that the use of a specially designed fortified spread (a specific Ready to Use Complementary Food [RUCF]) containing 500 kcal per 100 g as a complementary food for 12 months (from 6 months to 18 months of age) will reduce the incidence and prevalence of underweight and stunting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the Free University of Brussels approved on the 10th March 2009 (ref: P2009/060/B40620095963)
2. Ethics Committee of the Centre de Recherche of Science Naturelles (CRSN) approved on the 28th September 2008

Study design
Randomised controlled interventional trial

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
Underweight/stunting

Interventions
Intervention group: infants enrolled in the intervention group will receive 50 g of RUCF providing 250 kcal/day during 12 months (from the age of 6 to 18 months). The RUCF will be administered daily by the mother. Extension health workers serving the villages of participating children will visits the couples mother-infant biweekly.

Control group: Infants enrolled in the control group will receive 1 kg of UNIMIX flour per week. The porridge offered to infant should provide 250 kcal/day.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Prevalence of stunting at 12, 18 and 24 months of age.

Secondary outcome measures
1. Average daily breast milk intake at 6 and 9 months of age
2. Prevalence of exclusive breast feeding at 6 months of age
3. Mean change in anthropometric indices at 12, 18 and 24 months of age
4. Risks factors of stunting at 12 months of age
5. Incidence of diarrhoea at 12 months of age
6. Incidence of malaria at 12 months of age
7. Incidence of severe acute malnutrition at 12, 18 and 24 months of age
8. Proportion of children standing independently at 9 and 12 months of age
9. Proportion of children walking unassisted at 12 months of age
10. Mean cholesterol at 12 and 18 months of age
11. Mean triglycerides at 12 and 18 months of age
12. Mean haemoglobin at 12, 18 and 24 months of age

Overall study start date
15/11/2009

Completion date
30/12/2011

Eligibility

Key inclusion criteria
1. Full term born infants (gestational age greater than 37 weeks and birth weight greater than 2500 g)
2. Consent given

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants

677 infants per group (total: 1354 infants)

Key exclusion criteria
1. Bottle-fed children
2. Children with any malformations or neurological impairment

Date of first enrolment
15/11/2009

Date of final enrolment
30/12/2011

Locations

Countries of recruitment
Belgium

Congo, Democratic Republic

Study participating centre
Fond Tasnier 6
Genval
Belgium
1332

Sponsor information

Organisation
Irish Aid (Ireland)

Sponsor details
Department of Foreign Affairs
Bishops Square
Redmond Hill
Dublin
Ireland
2

Sponsor type
Charity

Website
http://www.dci.gov.ie

ROR

https://ror.org/03kyawa63

Funder(s)

Funder type
Charity

Funder Name
Irish Aid (Ireland)

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	01/05/2012		Yes	No