# The Ready to Use Complementary Food (RUCF) Study

Submission date [ ] Prospectively registered Recruitment status 08/11/2009 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 28/04/2010 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 19/06/2012 Pregnancy and Childbirth

### 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

### Protocol serial number

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

### Study type(s)

Quality of life

### 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(s)

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

### Key secondary outcome(s))

- 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

### 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** 

### Healthy volunteers allowed

No

### Age group

Child

#### Sex

All

### 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)

### **ROR**

https://ror.org/03kyawa63

# Funder(s)

### Funder type

Charity

### **Funder Name**

Irish Aid (Ireland)

# **Results and Publications**

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
Participant information sheet	Participant information sheet	11/11/2025 1	11/11/2025	No	Yes