

The Ready to Use Complementary Food (RUCF) Study

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| Submission date 08/11/2009 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 28/04/2010 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 19/06/2012 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 visit 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 | 11/11/2025 | No | Yes |