ISRCTN57733004 https://doi.org/10.1186/ISRCTN57733004

Identifying the effects of a complementary feeding guideline which has an emphasis on meat consumption, growth and breast milk intake in infants in Bogota, Colombia

Submission date
09/01/2012

Recruitment status
No longer recruiting

Registration date
23/02/2012

Overall study status
Completed

Last Edited
09/09/2015

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
Complementary feeding is the addition of foods to a baby's diet after an initial period of exclusive breastfeeding. By the time the baby is about 6 months old, breast milk on its own may not always be able to provide enough protein, iron and zinc for normal growth and development, so a good 'complementary' or extra supply of these nutrients is needed. It is often difficult to provide enough iron and zinc, especially for babies living in poor environments. Poor complementary feeding can lead to stunted growth and iron deficiency anaemia, which can affect the baby's development. In our previous studies we recorded infant feeding practices of mothers living in poor socio-economic circumstances in Bogota, Colombia. The results suggested that the diets given to these babies were often not ideal, and that many babies were not getting enough iron and zinc. Based on these results, we developed new complementary feeding guidelines for babies aged 6-12 months. The guidelines aim to improve the nutrition of the infant and emphasise the use of red meat as a good source of iron, zinc and protein. The new guidelines take into account the foods that are available, affordable and acceptable to mothers in this setting. In our study we aim to test the new guidelines with 180 babies from Bogota, Colombia.

Who can participate?
Healthy babies born at term (at least 37 weeks gestation) who are exclusively breastfed at 4 months of age will be eligible to take part, if their mother plans to continue breastfeeding until the infant is around 12 months of age.

What does the study involve?
Before the baby is enrolled in the study, a blood sample will be taken to make sure he or she is not anaemic. Any baby who is found to be anaemic will get treatment, and will not take part in the study. The babies will be randomly allocated at age 6 months to follow either the current

standard feeding advice in Bogota, or to use the new complementary feeding guidelines. They will be followed-up after 8, 10 and 12 months in the hospital clinic that they normally attend for their regular health checks and growth monitoring.

What are the possible benefits and risks of participating?
There are no likely risks or side effects from taking part in the study.

Where is the study run from?
The study will be run at two clinics in Bogota, Colombia (Suba and Fontibon). It is organised by investigators from the UCL Institute of Child Health, London and the Universidad Pontificia Javeriana, Bogota, Colombia.
When is the study starting and how long is it expected to run for?
March 2010 to August 2011.

Who is funding the study?
The study is funded by the Childhood Nutrition Research Centre, UCL Institute of Child Health, London and the Universidad Pontificia Javeriana, Bogota, Colombia.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
Version 1

Study information

Scientific Title
Randomised controlled trial to identify short-term effects of a complementary feeding guideline with an emphasis on meat consumption on iron and zinc status, growth and breast milk intake in infants aged 6-12 months in Bogota, Colombia.

Acronym

ComFeCol

Study objectives
A new complementary feeding guideline with an emphasis on increasing intake of red meat in infants living in poor socio-economic circumstances in Bogota, Colombia will result in improved iron and zinc status, improved linear growth, and improved development up to 12 months of age without adverse effects (decreased breast milk intake, excess weight gain, vitamin A excess); and the new guideline will be acceptable and affordable to families.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University College London Research Ethics Committee, 29/09/2009, ref: 2114/001
2. Javariena University, Bogota, 13/04/2009

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Nutrition in infants

Interventions
Randomised controlled trial of a new complementary feeding guideline compared to standard advice in healthy term infants living in poor circumstances in Bogota, Colombia.

Intervention group are asked to follow new guidelines for complementary feeding which incorporate written and oral advice to continue breastfeeding until at least 12 months, and for mothers to eat red meat at least 3 times per week. Advice is also given on other aspects of a healthy weaning diet together with suggestions on how to prepare and offer the foods.

Control infants receive the standard advice on breastfeeding and weaning provided by the usual healthcare team.

Intervention Type
Behavioural

Primary outcome(s)
1. Iron and zinc status at 12 months
2. Growth between 6 to 12 months:
2.1. Change in weight for length
2.2. Change in length for age SDS
3. Motor development at 12 months based on the WHO children's motor development (six gross

motor milestones)
4. Energy and nutrient intake, including breast milk intake from 6 to 12 months in a sub-sample (measured at 6, 8,10 and 12 months)

Key secondary outcome(s))
1. Mothers' opinions (in terms of acceptability and affordability) of the complementary feeding guidelines
2. Serum retinol as a safety outcome in the intervention group

Completion date
30/08/2011

Eligibility

Key inclusion criteria
1. Full term healthy children (>= 37 weeks)
2. Birth weight more than 2500g
3. Infant exclusively or predominantly breastfed at 4 months and planning to continue breastfeeding until 12 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
1. Preterm children (gestational age <37 weeks)
2. Children with congenital and chronic diseases
3. Children with anaemia (Hb<110g/dl) or infections at the time of randomisation
4. Birth weight < 2500g
5. Children who are Human immunodeficiency virus (HIV) positive
6. Infants whose mothers are likely to move from the area of the study in the short term

Date of first enrolment
01/03/2010

Date of final enrolment
30/08/2011

Locations

Countries of recruitment
United Kingdom

England

Colombia

Study participating centre
University College London
London
United Kingdom
WC1N1EH

Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
University/education

Funder Name
Childhood Nutrition Research Centre, University College London (UK)

Funder Name
Javariena University, Bogota (Colombia)

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	01/10/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes