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The effect of 4 or 6 months exclusive breastfeeding on infant breast-milk intake, growth and iron status

Submission date
03/02/2012

Recruitment status
No longer recruiting

Registration date
04/04/2012

Overall study status
Completed

Last Edited
25/08/2015

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
The World Health organisation (WHO) recommends that all infants should be exclusively breastfed for 6 months before starting solid foods (weaning). The quality of the research on which this recommendation is based is poor, particularly for developed countries. This is an important topic because the timing of weaning might affect a number of health outcomes in the baby such as the risk of anemia (low blood cell count, low hemoglobin) and allergy. The aims of this study is to test whether mothers who are breastfeeding their healthy term baby will agree to be randomly allocated to exclusively breast-fed their baby for 4 or 6 months, and to test whether being exclusively breast-fed for either 4 or 6 months affects how much breast-milk the infant drinks at 6 months, the infant's growth pattern or the likelihood of the infant getting low iron stores and anaemia.

Who can participate?
Infants living in the areas served by 7 health clinics in Iceland can take part in the study if they are born at term (37 weeks or more), are healthy, and are exclusively breast-fed at the age of 4 months.

What does the study involve?
The study compared infants who were exclusively breast-fed for 6 months with those who were exclusively breast-fed for 4 months who then started solid foods together with continued breastfeeding.

What are the possible benefits and risks of participating?
No side effects are expected as a result of participation in the study. There are no particular benefits to the infant from taking part in the study, although mothers will get extra breastfeeding advice if they need it, and the infant will be checked for anaemia at the age of 6 months and could be treated if a problem is found.

Where is the study run from?
The study took place in 4 health centres in Iceland (2 in Reykjavik; 1 in Akranes; 1 in Hafnarfjordur)

When is the study starting and how long is it expected to run for?
The study recruited infants from November 2007 to November 2009, with 6 month follow-up finished in May 2010.

Who is funding the study?
Mead Johnson Nutritionals and Eimskip Fund of the University of Iceland.

Who is the main contact?
Dr Mary Fewtrell
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2006-P-001453/1; MGH

Study information

Scientific Title
Breastfeeding and child health: randomized controlled trial on the impact of age of introduction of weaning foods

Acronym
ICEAGE

Study objectives
1. It is feasible to randomise mothers to exclusively breast-feed for 4 or 6 months
2. The duration of exclusive breastfeeding and the age at introduction of complementary (weaning) foods will affect infant breast-milk intake, infant growth and infant iron status at age 6 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Data Protection Authority and National Bioethical Committee in Iceland approved on 04/27/2007 ref: 02-164-V3-S1
2. Partners Health System IRB (US) approved on 10/25/2007, ref: 2006-P-001453/1

Study design
Parallel-group masked randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

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
Healthy term infant feeding

Interventions
Exclusive breastfeeding for 6 months compared to exclsuive breastfeeding to 4 months with introduction of solid foods alongside continued breastfeeding.

Intervention Type
Behavioural

Primary outcome measure
1. Feasibility
1.1 Proportion of mothers that will breastfeed exclusively for 6 months
1.2 Proportion of mothers randomized at 4 months (from those invited to participate)
2. Measurements at 6 months
2.1 Infant breast milk intake (by stable isotopes)
2.2 Infant growth
2.3 Infant iron status

Secondary outcome measures
1. Infant food intake
2. Infant body composition
3. Occurrence of upper respiratory infections and diarrheal episodes (dichotomous variables)

Overall study start date
01/11/2007

Completion date
31/05/2010

Eligibility

Key inclusion criteria
1. Healthy term infant (>37 weeks gestation)
2. No health issues affecting growth
3. No other siblings enrolled in the study
4. Exclusively breast-fed at age 4 months

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
100 infants completing study to 6 months, from 7 healthcare centers

Key exclusion criteria
Infant not exclusively breast-fed at age 4 months

Date of first enrolment
01/11/2007

Date of final enrolment
01/11/2009

Locations

Countries of recruitment
Iceland

United States of America

Study participating centre
Massachusetts General Hospital
Boston
United States of America
MA 02114

Sponsor information

Organisation
Mead Johnson Nutritionals (USA)

Sponsor details
c/o - Chelsea Hunter / Tim Cooper
2400 West Lloyd Expressway B201
Evansville, In
United States of America
IN47721

Sponsor type
Industry

Website
http://www.meadjohnson.com/

ROR
https://ror.org/05p4pn188

Funder(s)

Funder type
Industry

Funder Name
Mead Johnson Nutrition

Alternative Name(s)

Mead Johnson

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Eimskip Fund of the University of Iceland (Iceland)

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	01/12/2012		Yes	No
Results article	results	01/05/2014		Yes	No