

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

<b>Submission date</b> 03/02/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 04/04/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/08/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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-feed 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

Prof Ronald Kleinman

### Contact details

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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 exclusive 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?
<a href="#">Results article</a>	results	01/12/2012		Yes	No
<a href="#">Results article</a>	results	01/05/2014		Yes	No