

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	<input type="checkbox"/> Prospectively registered
Registration date 04/04/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/08/2015	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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-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

m.fewtrell@ich.ucl.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Ronald Kleinman

Contact details

Physician in Chief, MassGeneral Hospital for Children

Chair, Department of Pediatrics

Chief, Pediatric Gastrointestinal and Nutrition Unit

Massachusetts General Hospital

Charles Wilder Professor of Pediatrics

Harvard Medical School

CPZS 578

175 Cambridge Street

Boston

United States of America

MA 02114

-

rkleinman@partners.org

Additional identifiers

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

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

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