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The role and effect of limited formula use on breastfeeding and its discontinuation

Submission date 26/08/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 07/09/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 10/10/2023	**Condition category** Other	[X] Individual participant data

Plain English summary of protocol

Background and study aims
It has long been thought that breastfeeding is the best way to feed new babies, as it provides hormones and disease-fighting substances that protect babies from illness. Producing enough milk for a new baby puts a great deal of strain on the mother's body and, often, new mothers are often unable to produce enough milk to meet all of their baby's needs during the first few months after birth. Breast milk is therefore sometimes accompanied with small amounts of formula, in order to make sure that babies are gaining enough weight. The pros and cons of supplementing breast milk with formula are widely debated, as some experts believe that bottle-feeding too early can lead to babies refusing to breastfeed. This study aims to find out whether giving babies very small amounts of formula at the same time as breast feeding will have an effect on the amount of babies who are being breastfed in the short and long term.

Who can participate?
Healthy babies with a normal birth weight, whose mothers are planning on breast feeding for a long time.

What does the study involve?
Mother and infant pairs are randomly allocated into two groups. The babies in the first group (intervention group) are given a set volume of 10ml of formula after each breastfeed until the mother is able to produce enough milk. The babies in the second group (control group) are exclusively breastfed, and receive no additional formula, unless the baby has lost more than 10% of its body weight since birth, is irritable, or if the mother specifically requests that the baby receive extra formula. Information about the babies' feeding habits, as well as any weight changes are recorded by a nurse at 3 and 6 months after birth.

What are the possible benefits and risks of participating?
Comparing the two groups will help to find out if giving controlled amounts of formula may help support mothers and their babies in establishing breastfeeding and keeping the rates of breastfeeding up in longer term (3 months and 6 months). There are no known risks to participating as the comparison is with a standard approach to breastfeeding and formula feeding during hospitalisation after birth.

Where is the study run from?
Institute for the Care of Mother and Child (Czech Republic)

When is the study starting and how long is it expected to run for?
December 2013 to June 2015

Who is funding the study?
The Charles University Research Development Schemes (Czech Republic)

Who is the main contact?
Professor Zbynek Stranak

Contact information

Type(s)
Scientific

Contact name
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147 00

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A prospective, randomized trial comparing the use of controlled limited formula (CLF) to a standard approach (SA) for efficiency and duration of breastfeeding in neonates

Study objectives

We hypothesize that early limited formula feeds in infants with early weight loss will not adversely affect the rate of breastfeeding in the short and long term.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institute for the Care of Mother and Child, 19/12/2013, ref: 2013-12-19-3

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Breastfeeding

Interventions
Infants in the CLF group (intervention group) are given a set volume of 10 ml of formula after each breastfeed until adequate milk production begins. Infants in the SA group (control group) are exclusively breastfed. In the SA group supplemental feeds are administered only in indicated cases (excessive weight loss of more than 10%, irritability of the newborn and on the mother's specific request).
Duration of intervention: formula administration from enrolment (see inclusion criteria) until the onset of lactation.
Follow-up for all treatment arms is the same: at point of discharge, at 3 months and at 6 months of the infant's age

Intervention Type
Other

Primary outcome measure
Breastfeeding rate at 3 month of age (value: Yes or No or to some extent)

Secondary outcome measures

1. Exclusive breastfeeding at 3 months of age (value: Yes or Not)
2. Breastfeeding at 6 months of age (value: Yes or No or to some extent)
3. Exclusive breastfeeding at 6 months of age (value: Yes or Not)
4. Weight loss - the loss of weight during birth hospitalization (calculated as actual weight/birth weight x 100)
5. Weight loss - the loss of weight during birth hospitalization (calculated as actual weight/birth weight x 100)

Overall study start date
01/12/2013

Completion date
01/06/2015

Eligibility

Key inclusion criteria
1. Healthy term neonates with weight loss ≥5 per cent between 24th and 48th hour of life
2. Singleton
3. Eutrophic with birth weight between 2500 – 4000 grams
4. Born after uncomplicated pregnancy and delivery
5. No severe congenital defects
6. Mothers are planning to breastfeed for a long time

Participant type(s)
Patient

Age group
Neonate

Lower age limit
1 Days

Upper age limit
2 Days

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Mother-infant pairs with serious maternal complications (hypertension, diabetes, systemic diseases, drug abuse)
2. Mothers using therapy that might affect breastfeeding, e.g. antidepressants

Date of first enrolment
01/01/2014

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
Czech Republic

Study participating centre
Institute for the Care of Mother and Child
Podolske nabrezi 157
Prague
Czech Republic
147 00

Sponsor information

Organisation
Institute for the Care of Mother and Child

Sponsor details
Podolske nabrezi 157
Prague
Czech Republic
147 00

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03zd7qx32

Funder(s)

Funder type
University/education

Funder Name
The Charles University Research Development Schemes (PRVOUK32)

Results and Publications

Publication and dissemination plan
We plan to submit the manuscript to international journals.

Intention to publish date
31/10/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/02/2016		Yes	No
Dataset		26/02/2016	10/10/2023	No	No
Protocol (other)		26/02/2016	10/10/2023	No	No