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Can bovine colostrum added to infant formula prevent diarrheal and respiratory diseases?

Submission date
05/10/2018

Recruitment status
No longer recruiting

Registration date
20/12/2018

Overall study status
Completed

Last Edited
11/01/2019

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Respiratory infections are a major cause of disease and death in developing countries. Diarrhea is also a major killer in children under five and recurrent diarrhea affects nearly 20% of the population. Fighting against these disease is a matter of the highest importance for mothers all over the world. Breastfeeding is the most cost-effective way to protect children against infectious disease, because milk contains substances that fight infection. Colostrum is the first milk produced after delivery of a baby. It contains concentrated nutrients and antibodies. Bovine colostrum (BC) from cows' milk has high levels of anti-infective components that are similar to the substances in human colostrum. The daily use of BC has been reported to have a protective role for infantile gastrointestinal disease due to its direct effect on enhancing immunity in the gut. Studies in infants indicate the possible treatment and preventive role of oral BC against many infectious diseases of infants. However, there is no research to study the preventive role of BC on infectious disease in formula milk feeding infants. The aim of this study is to look at the effect of BC on the prevention of diarrheal and respiratory disease in infants.

Who can participate?
Infants aged 6-9 months who are fully formula feeding after birth

What does the study involve?
Infants will be randomly assigned to one of the two groups, either the intervention or the control group. Infants in the intervention group will be given a commercially available BC sachet once a day for 3 months, which can be mixed with 30-50 ml of warm water (below 40), or added to milk, rice cereal, soup, rice porridge and other foods. Infants in the control group will not be provided with any BC sachets. Basic information will be collected, including family socioeconomic status, levels of main caregivers, family monthly income, and use of vitamin /mineral supplement before the study. Parents will be requested to inform the health care workers if their babies experience any symptoms of diarrheal or respiratory disease. Before and after the study, the babies weight, length and head circumference will be measured and babies feces will be analysed.

What are the possible benefits and risks of participating?
During the trial, infants' parents will obtain knowledge about healthcare, disease development

and disease monitoring for their babies. The possible risk to participants is that infants may be allergic to BC; however, any infants with a personal or family history of allergies to cow's milk or intact infant formula, eczema, allergic rhinitis or asthma will not be able to take part.

Where is the study run from?
Angel Children's Hospital Chengdu (China)

When is the study starting and how long is it expected to run for?
March 2017 to May 2018

Who is funding the study?
Self-funded

Who is the main contact?
Dr. Ke Chen
263662086@qq.com

Contact information

Type(s)
Scientific

Contact name
Dr Ke Chen

ORCID ID
http://orcid.org/0000-0001-7455-0900

Contact details
No.1617, Riyur Avenue, Qingyang District
Chengdu
China
610000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The role of bovine colostrum as prophylaxis for respiratory infections and diarrhea in formula feeding infants after birth

Study objectives
We addressed the hypothesis that formula fed infants supplemented with bovine colostrum (BC) will have reduced morbidity of diarrhea and respiratory tract infections (RTIs) compared with infants who only received formulas without bovine colostrum

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee of the Angel Children's Hospital Chengdu in Sichuan province, China, 01/07/2017, no reference number available

Study design
Interventional multi-centre blank-controlled randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Infants fully formula feeding after birth

Interventions
Eligible infants were randomly assigned to one of the two intervention groups. Infants in the intervention group (IG) were given a commercially available bovine colostrum (BC) sachet (Hainan Govking High-Tech Dairy Industry Co., Ltd, Haikou, China, Product Batch Number: D7010) once a day, which contained a bovine IgG concentration of 200 mg/g per sachet. Each sachet (1.0 g) can be mixed with 30-50 ml of warm water (below 40°C), or added to milk, rice cereal, soup, rice porridge and other foods. Infants in the control group (CG) were given no BC sachet. The intervention duration was three months.

Intervention Type
Supplement

Primary outcome measure
The following are assessed using patient interviews throughout the 3 month intervention period:
1. Morbidity of diarrhea
2. Respiratory tract infections

Secondary outcome measures
The following are assessed at the baseline and after 3 months:
1. Duration of respiratory-related illnesses, assessed using patient interviews
2. Duration of diarrhea-related illnesses, assessed using patient interviews
3. Growth levels of infants, assessed by measuring their weight, length and head circumference
4. Family functional scores assessed using PedsQL™ 2.0 Family Impact Module
5. Levels of the following, assessed using ELISA of fecal samples:
5.1. IgA
5.2. Calprotectin
5.3. Total fatty acid

Overall study start date
10/03/2017

Completion date
01/05/2018

Eligibility

Key inclusion criteria
1. Apparent good health without common obstetric risk factors
2. Full term with 37-42 weeks' gestation at birth with birth weight of more than 2500 g
3. Previously fully formula feeding after birth to 6-9 months at recruitment
4. Parent or guardian approval for participating in all aspects of the study
5. Parent or guardian agreement to avoid additional BC and probiotic products during the investigation

Participant type(s)
Healthy volunteer

Age group
Child

Sex
Both

Target number of participants
192

Key exclusion criteria
1. History of severe, persistent, or chronic diarrhea
2. Severe malnutrition
3. Serious infections requiring hospitalization in the month prior
4. Serious chronic illness
5. Personal or family history of allergy to cow's milk or intact infant formula
6. Eczema
7. Allergic rhinitis
8. Asthma

Date of first enrolment

01/08/2017

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
China

Study participating centre
BaoXing Center for disease control and Prevention
Yaan
China
625700

Study participating centre
Liucheng Community Healthcare Center
Chengdu
China
610000

Study participating centre
Caojiaxiang Community Healthcare Center
Chengdu
China
610000

Study participating centre
Hehuachi Community Healthcare Center
Chengdu
China
610000

Study participating centre
Jitouqiao Community Healthcare Center
Chengdu
China
610000

Sponsor information

Organisation
Chengdu Women's and Children's Central Hospital

Sponsor details
No.1617, Riyue Avenue, Qingyang district
Chengdu
China
610000

Sponsor type
Hospital/treatment centre

Website
http://www.wcch.cn

ROR
https://ror.org/008x2am79

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
We plan to submit the paper to SCI this year.

Intention to publish date
01/01/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		08/11/2018	20/12/2018	No	No