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Trial of lactoferrin for prevention of infections in very premature babies

Submission date
04/10/2011

Recruitment status
No longer recruiting

Registration date
14/02/2012

Overall study status
Completed

Last Edited
07/03/2016

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Lactoferrin is a major protein in mammalian milk and is important in defence against infections. Premature babies receive very little lactoferrin. Premature babies are at very high risk of catching bacterial infections while they are in hospital. These infections can be fatal or they can have impacts on future development of the baby. One previous study suggested that lactoferrin derived from cows milk may reduce the risk of these fragile babies being infected. This study is being performed to confirm the previous study results, and to see if a further large multi-center trial can be performed in Canada.

Who can participate?
Preterm infants in the neonatal unit at Sainte Justine University Health Center, who are born before 31 weeks of gestation.

What does the study involve?
Babies will be randomly divided into two groups on the day that they first receive milk feeds (usually in the first few days of life). The intervention group will get lactoferrin every day mixed into their milk feeds, continuing until they are at 36 weeks or until they leave hospital if that occurs first. The control group will receive milk without added lactoferrin. There are no additional blood tests needed. This is a masked trial: lactoferrin does not change the appearance of the milk and we will not know which baby is in which group until the trial is finished. Any baby who develops signs of an infection will have the usual blood cultures taken, just as they would if they were not in the study. The main question we are asking is whether the babies are more likely to leave the hospital alive without an infection in one group or the other.

What are the possible benefits and risks of participating?
There are no known risks from receiving lactoferrin, no side effects have been described, and it does not appear to be absorbed from the intestines. All babies will receive usual medical care.

Where is the study run from?
Sainte Justine University Hospital, Montreal, Canada

When is the study starting and how long is it expected to run for?
The study started in November 2011 and ran for 6 months.

Who is funding the study?
Research Center of Sainte Justine, Canada

Who is the main contact?
Dr Keith J Barrington
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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
N/A

Study information

Scientific Title
Randomized controlled pilot trial of lactoferrin for prevention of infections in very preterm newborns

Acronym
LACUNA (LACtoferrin Use in NeonAtes)

Study objectives
In infants who are born at gestational ages of 23 0/7 to 30 6/7 weeks, administration of bovine lactoferrin commencing within the first 48 hours of life, and continuing until 36 weeks post-

menstrual age or to hospital discharge if sooner, compared with control, increases the probability of survival without a proven Healthcare-Associated Infections (HCAI) to discharge from hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre randomized blinded clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Healthcare-associated infections in preterm infants

Interventions
Infants allocated to the treatment group will receive 100 mg per day of bovine lactoferrin, divided into two doses per day. This will start on the first day of enteral feeding (day of enrolment) or at the latest at 48 hours of age and they will receive it daily until 36 weeks post-menstrual age (PMA) or discharge home.

Control infants receive milk without lactoferrin

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Death or at least one HCAI before discharge home
2. Tolerance of lactoferrin

Secondary outcome measures

1. Infections per 1000 patient days. Because some infants may experience more than one HCAI during their stay, and others may be transported to level 2 step-down units prior to discharge home, other analyses of infection rates are required. Calculation of the number of infections per 1000 patient days corrects for some of these factors.
2. Necrotizing Enterocolitis (NEC): The diagnostic criteria for NEC which will be used as the primary outcome will be the modified Bells criteria, stage 2 or more, i.e. a clinical diagnosis of necrotizing enterocolitis with, in addition pneumatosis intestinalis or portal venous gas, or a surgical or autopsy diagnosis of NEC.
3. Surgical intervention for NEC, or spontaneous intestinal perforation will be recorded
4. Death ascribed to acute effects of sepsis

Overall study start date
01/11/2011

Completion date
30/04/2012

Eligibility

Key inclusion criteria
Preterm infants in the neonatal intensive care unit (NICU) at CHU Sainte Justine, with a gestational age at birth of 23 0/7 to 30 6/7 weeks who are less than 48 hours of age

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
80

Key exclusion criteria
Intestinal abnormailities preventing enteral feeding, such as gastroschisis

Date of first enrolment
01/11/2011

Date of final enrolment
30/04/2012

Locations

Countries of recruitment
Canada

Study participating centre
CHU Sainte Justine
Montreal
Canada
H3T 1C5

Sponsor information

Organisation
Research Center of CHU Sainte-Justine [Centre de Recherche de CHU Sainte-Justine] (Canada)

Sponsor details
3175 Chemin de la Côte-Sainte-Catherine
Québec
Montreal
Canada
H3T 1C5

Sponsor type
Research organisation

Website
http://www.chu-sainte-justine.org/recherche/

ROR
https://ror.org/01gv74p78

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Canada)

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	01/08/2016		Yes	No