ISRCTN66482337 https://doi.org/10.1186/ISRCTN66482337

# 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
keith.barrington@umontreal.ca

# Contact information

### Type(s)
Scientific

### Contact name
Dr Keith Barrington

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# Additional identifiers

### Protocol serial number
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

### Study type(s)
Treatment

### 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(s)
1. Death or at least one HCAI before discharge home
2. Tolerance of lactoferrin

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Neonate

### Sex
All

### 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
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## Sponsor information

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

### ROR
https://ror.org/01gv74p78

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded (Canada)

# 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 | 01/08/2016 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |