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# Donor milk for improved neurodevelopmental outcomes

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 24/06/2010 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 10/08/2010 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 10/08/2020 | Neonatal Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**
NCT02759809

**Secondary identifying numbers**
MP-102638

# Study information

## Scientific Title
Donor human milk versus preterm formula as a substitute for mothers' own milk for feeding very low birth weight infants

## Acronym
DoMINO

## Study objectives
Our primary research hypothesis is that very low birth weight (VLBW) infants fed donor milk as a supplement to mothers' own milk for 90 days or until hospital discharge, whichever comes first, will have an improved cognitive composite score at 18 - 24 months corrected age (CA) compared to infants fed preterm formula as a supplement.

Our secondary hypotheses are that the use of donor milk compared to formula, as a supplement to mothers' own milk, will:
1. Reduce a composite of death, necrotising enterocolitis (NEC), late onset sepsis, chronic lung disease and severe retinopathy of prematurity
2. Support growth
3. To improve language and motor development

Exploratory research questions are will the use of donor milk, as a supplement to mothers' own milk:
1. Influence feeding tolerance and nutrient intake?
2. Have an acceptable cost effectiveness from comprehensive societal perspective?

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Research Ethics Board for The Hospital for Sick Children, ref: 1000017662

## Study design
Pragmatic multicentre double-blind randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Quality of life

## 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
Neurodevelopmental outcomes

## Interventions
Treatment Group:
Infants randomised to the intervention group will receive donor milk when mothers' own milk is unavailable. Infants will continue to receive donor milk after transfer to a participating Level II NICU for 90 days after randomisation or discharge home, whichever occurs first.

Control Group:
Infants randomised to the control group will receive formula designed for preterm infants when mothers' own milk is unavailable. Infants will continue to receive formula after transfer to a participating Level II NICU for 90 days after randomization or discharge home, whichever occurs first.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure
Cognitive composite score on the Bayley Scales of Infant and Toddler Development-III (BSID-III) at 18 - 24 months corrected age.

## Secondary outcome measures
1. Morbidity/mortality
2. Composite of death, NEC, late onset sepsis, chronic lung disease or severe retinopathy of prematurity (ROP)
3. Growth (Secondary):
3.1. Weight (g/kg/d), length (mm/wk) and head circumference (mm/wk) gain
3.2. Weight-for-age, length-for-age and head circumference-for-age z-scores
4. Development (Secondary):
4.1. Language and motor composite scores on the BSID-III at 18-24 months corrected age
5. Feeding Tolerance and Nutrient Intake (Exploratory)
5.1. Days to full enteral feeding (150 ml/kg/d)
5.2. Days feedings withheld
5.7. Estimated energy and select nutrient intakes (protein, fat, calcium, phosphorus, iron, zinc)
6. Growth and Breastfeeding (Exploratory)
6.1. Weight-for-age, length-for-age and head circumference-for-age z-scores to 18-24 months corrected age
6.2. Duration (days) of human milk feeding (mothers own milk)
6.3. Exclusivity of human milk feeding (mothers own milk) at each infants 4, 6 and 12 months corrected age
7. Cost effectiveness (medical and non-medical) from a societal perspective (Exploratory)
Added 20/09/2017: 8. Gut microbiome characterization (Exploratory

## Overall study start date

14/09/2010

### Completion date
17/07/2015

## Eligibility

### Key inclusion criteria
1. Day 1 to 4 of life
2. Less than 1500 g birth weight
3. Enteral feeding is expected to be initiated in the first 7 days of life

### Participant type(s)
Patient

### Age group
Neonate

### Sex
Both

### Target number of participants
352

### Total final enrolment
363

### Key exclusion criteria
1. Infants with serious congenital or chromosomal anomalies that may contribute to serious developmental outcome
2. Asphyxia (hypoxia or ischaemia) as defined by all of:
2.1. Severe metabolic or mixed acidaemia (pH less than 7.00 or base deficit less than -16) on an umbilical cord arterial blood sample or neonatal blood gas within first hour of life
2.2. Apgar score of 0 - 3 for greater than 5 minutes
2.3. Multi-organ system dysfunction within 72 hours of birth
3. Enrolment in any other clinical study affecting nutritional management during the feeding intervention
4. Reasonable potential that the infant will be transferred to a Neonatal Intensive Care Unit (NICU) or Level II NICU where the study protocol will not be continued

### Date of first enrolment
14/09/2010

### Date of final enrolment
19/12/2012

## Locations

### Countries of recruitment
Canada

**Study participating centre**
**The Hospital for Sick Children**
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# Sponsor information

**Organisation**
The Hospital for Sick Children

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**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/057q4rt57

# Funder(s)

**Funder type**
Government

**Funder Name**
Canadian Institutes of Health Research (CIHR) (Canada) (MP-102638)

**Alternative Name(s)**
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

**Funding Body Type**
Government organisation

### Funding Body Subtype
National government

### Location
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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 13/05/2014 | | Yes | No |
| Results article | results | 08/11/2016 | | Yes | No |
| Results article | results | 01/03/2018 | | Yes | No |
| Results article | results | 01/12/2019 | 20/09/2019 | Yes | No |
| Results article | results | 01/02/2020 | 11/10/2019 | Yes | No |
| Results article | follow up results | 01/02/2020 | 10/08/2020 | Yes | No |