

Donor milk for improved neurodevelopmental outcomes

Submission date 24/06/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 10/08/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/08/2020	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02759809

Protocol serial number
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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

Toronto

Canada

M5G 1X8

Sponsor information**Organisation**

The Hospital for Sick Children

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, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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
Protocol article	protocol	13/05/2014		Yes	No