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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