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Effect on body and brain development of feeding very premature babies with breast milk containing different supplements

Submission date
10/01/2015

Recruitment status
No longer recruiting

Registration date
11/02/2015

Overall study status
Completed

Last Edited
18/05/2018

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Human milk is the ideal food for all human babies and has a nutrient composition ideal for babies that have been born at full term. However, the protein and mineral content of human milk may not be sufficient for premature babies as they need more protein, sugars and fats for growth and development. Lack of nutrition of premature babies can lead to slower than usual growth and there are concerns regarding both the short and long-term neurodevelopment (brain and central nervous system development) of these babies. In this study, we are going to observe very premature babies, fed with their mother's milk with blind macro nutrient content, fortified with standard human milk fortifier and protein supplementation according to ESPGHAN recommendations. We expect to find variation in the content of these nutrients and to see if that has some influence in body composition measured by somatometry and air plethismography as well as in neurodevelopment at 12 and 18 months of age.

Who can participate?
Premature babies of less than 34 weeks gestational age.

What does the study involve?
Immediately after discharge from hospital, the body composition of the babies included in the study is measured by plethismography, generally in the same day of other standard study. They all receive standard neonatal and after discharge care. At 12 months and again at 18 months, the neurodevelopment of all babies are assessed.

What are the possible benefits and risks of participating?
The study may give some insight in the need of macro-nutrient evaluation of feeding premature babies and may result in adjusting the nutrient content of supplements given. There are no expected risks, as it is an observational study and the follow up is the same for all the babies.

Where is the study run from?
Lisbon Central Hospital Centre (Portugal)

When is the study starting and how long is it expected to run for?
February 2014 to December 2014

Who is funding the study?
Milupa Portugal, Lda (Portugal)

Who is the main contact?
Dr Israel Macedo

Contact information

Type(s)
Public

Contact name
Dr Israel Macedo

Contact details
Alam Qta Sto Antonio 5-N3-2Esq
Lisbon
Portugal
1600-675

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2

Study information

Scientific Title
Effect of different composition of human milk and its fortification in body composition and neurodevelopment in a cohort of very preterm infants: a observational cohort study

Study objectives
Preterm infants feed in the first weeks of life with recommended but different amounts of protein have different body composition (measured as % of FFM/FM) at 40 weeks gestational corrected age and different psychomotor development in the medium term.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Hospital Board Ethics approval, 16/05/2012, ref: Nr 116/2012
2. A Comissão de Ética da NMS|FCM-UNL, 01/10/2015, ref: 75/2014/CEFCM

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files (available in Portuguese)

Health condition(s) or problem(s) studied
Body composition, BSDI II at 12 and 18 months

Interventions
1. Normal variation in human milk composition
2. Blind fortification plus protein supplementation - caregivers and evaluators blind to macronutrient composition.

Intervention Type
Supplement

Primary outcome measure
1. Body composition by plethysmography at 40 weeks
2. Bayley Scales of Infant Development II (BSDI II) at 18 months

Secondary outcome measures
Neonatal morbidities

Overall study start date
01/02/2014

Completion date
28/02/2015

Eligibility

Key inclusion criteria
Preterms with less 34 weeks gestational age

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Congenital malformations
2. Formula feeding
3. Inability to achieve full enteral feeding
4. Parents inability to understand informed consent

Date of first enrolment
01/02/2014

Date of final enrolment
28/02/2015

Locations

Countries of recruitment
Portugal

Study participating centre
Lisbon Central Hospital Centre (Centro Hospitalar Lisboa Central (MAC and HDE))
Rua Viriato 1069
Lisbon
Portugal
1069

Sponsor information

Organisation
Portuguese Neonatal Society

Sponsor details
c/o Rosalina Barroso, MD
Hospital Prof. Doutor Fernando Fonseca
Amadora

Portugal
2720-276

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00snfqn58

Funder(s)

Funder type
Industry

Funder Name
Milupa Portugal, Lda

Results and Publications

Publication and dissemination plan
1. At least two publications
2. PhD thesis presentation

Results published in 2017 thesis https://run.unl.pt/bitstream/10362/35458/1/Macedo%20Israel%20TD%202018.pdf

Intention to publish date
31/03/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		29/01/2014	04/10/2016	No	Yes
Results article	results	01/07/2018		Yes	No