

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/02/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 18/05/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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 plethysmography 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 plethysmography, 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/00snfq58>

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