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Post-discharge growth, body composition and neurodevelopment outcome of very preterm infants in relation to two formulas with different composition in terms of energy and protein content

Submission date	Recruitment status	[X] Prospectively registered
15/07/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/04/2014	Pregnancy and Childbirth	

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

Secondary identifying numbers
N/A

Study information

Scientific Title
Post-hospital discharge feeding for very preterm infants: effects of standard compared with enriched milk formula on growth, body composition and neurodevelopment outcome - a single centre randomised controlled trial

Study objectives
The goal is to evaluate the effects on post-discharge growth, body composition and neurodevelopment outcome of two distinct strategies for post-discharge nutrition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee FONDAZIONE IRCCS Ospedale Maggiore Policlinico Mangiagalli Regina Elena approved on the 7th July 2009

Study design
Single centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Pre-term infant post-discharge nutrition and body composition

Interventions
Infants will be enrolled at term equivalent age and will be prospectively followed-up from term to 12 months of corrected age.

At term equivalent age infants will be randomised in four groups:
Group 1: infants born average for gestational age (AGA) fed nutrient-enriched post-discharge formula (2.2 g/100 ml; 75 kcal/100 ml)

Group 2: infants born AGA fed standard formula (1.4 g/100 ml; 67 kcal/100 ml)
Group 3: infants born small for gestational age (SGA) fed nutrient-enriched post-discharge formula (2.2 g/100 ml; 75 kcal/100 ml)
Group 4: infants born SGA fed standard formula (1.4 g/100 ml; 67 kcal/100 ml)

From term up to the six month, infants will be fed a nutrient-enriched post-discharge or standard formula (according to randomisation) on demand and will be given no other foods. Parents will be instructed to record the daily quantities of milk consumed by the infants in a diary. The average daily energy and protein intakes (expressed as kcal/kg body weight/d and g /kg body weight/d, respectively) will be calculated at each study visit time.

Infants will enter a follow-up program that consists of assessment of periodic growth and body composition assessments (by means of an air displacement plethysmography system and the four skinfold thicknesses [triceps, biceps, subscapular and suprailiac], with use of a skinfold calliper) at term corrected age, 15 d, 1, 3, 5, 6 and 12 months of corrected age. Neurodevelopmental outcome will be also assessed by means of a neurofunctional evaluation (at 40 weeks, 3, 6, 12 months' corrected age) and the Griffith Scale (at 12 months of corrected age).

Reference group:
The reference group will be represented by infants fed human milk who will not be randomised but will undergo the growth, body composition and neurodevelopment assessment according to the protocol.

In order to detect a 5% difference in fat mass among groups at a significance level of 0.05 and 80% power, 40 infants are needed for each group. Taking into account lost-to-follow up /withdrawal, a total number of 160 will need to be recruited for the study. Taking into account lost-to-follow up/withdrawal, a total number of 184 will need to be recruited for the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Body composition (assessed by means of an air plethismography-Pea Pod and the four skinfold thicknesses [triceps, biceps, subscapular and suprailiac] with use of a skinfold calliper), at term corrected age, 15 d, 1, 3, 5, 6 and 12 months of corrected age
2. Growth (weight, length and head circumference assessed at term corrected age, 15 d, 1, 3, 5, 6 and 12 months of corrected age)

Secondary outcome measures
Neurodevelopment outcome (by means of a neurofunctional evaluation at 40 weeks, 3, 6, 12 months' corrected age) and the Griffith Scale (at 12 months of corrected age).

Overall study start date
15/09/2009

Completion date
15/09/2013

Eligibility

Key inclusion criteria
1. Birth weight less than 1500 g
2. Gestational age less than 33 weeks
3. Caucasian race, either sex
4. Informed consent signed by infants' parents or legal guardian

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
184

Key exclusion criteria
1. Congenital diseases
2. Chromosomal abnormalities
3. Severe gastrointestinal diseases (i.e. necrotising enterocolitis)
3. Metabolic and or endocrine disease
4. Severe brain injury
5. Chronic lung disease

Date of first enrolment
15/09/2009

Date of final enrolment
15/09/2013

Locations

Countries of recruitment
Italy

Study participating centre
Fondazione IRCCS Ospedale Maggiore Policlinico Mangiagalli Regina Elena
Milan
Italy
20122

Sponsor information

Organisation
Fondazione IRCCS Ospedale Maggiore Policlinico Mangiagalli Regina Elena (Italy)

Sponsor details
Dipartimento di Scienze Materno-Infantili
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Sponsor type
Research organisation

Website
http://www.mangiagalli.it

ROR
https://ror.org/016zn0y21

Funder(s)

Funder type
Research organisation

Funder Name
Fondazione IRCCS Ospedale Maggiore Policlinico Mangiagalli Regina Elena (Italy)

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?
Results article	results	01/11/2012		Yes	No

Results article	results	19/03/2014	Yes	No