ISRCTN99801051 https://doi.org/10.1186/ISRCTN99801051

Assessment of growth and body composition in preterm infants in relation to two different protein intakes: a randomised controlled trial

Submission date	Recruitment status	[ ] Prospectively registered
31/07/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/09/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/09/2008	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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

Study objectives
The goal is to evaluate the safety and the effects on neonatal growth and body composition of two distinct strategies (intervention and control) for parenteral nutrition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethical Committee FONDAZIONE IRCCS Ospedale Maggiore Policlinico Mangiagalli Regina Elena on the 24th March 2006.

Study design
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
Preterm infant nutrition and body composition

Interventions
To detect a difference of 3.0 g/kg per day in weight gain between the two treatment groups (a = 0.25; power = 80%, assuming SD = 2.0 g/kg per day), 9 patients are required for each group.

Preterm infants will be randomised to receive two different schedules of NPT: high or low protein intake for two weeks. The high protein intake consists of at maximum 3.5 g/Kg/d starting from 2.5 g/Kg/d and the low protein intake consists of 2.5 g/Kg/d starting from 1.5 g/Kg /d.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Safety/tolerance:
1. Haemo-gas analysis twice a week for the first 15 days
2. Blood urea nitrogen and serum ammonium on the 1st day of life, on the 4th/5th, on the 7th /8th and 15th day of life
3. Blood amino acid profile on the 1st day of life (before starting NPT) and on the 4th/5th and 15th day of life

Secondary outcome measures
Efficacy:
1. Body composition (assessed by means of deuterium and air plethismography-Pea Pod) at birth, at 15 days of life and at 36 weeks of post-conceptional age
2. Growth (weight assessed daily, length and head circumference assessed weekly)
3. Anabolism assessed by means of nitrogen balance on 2nd, 5th, and 8th day of life
4. Blood amino acid profile on the 1st day of life (before starting NPT) and on the 4th/5th and 15th day of life

Overall study start date
01/09/2008

Completion date
01/06/2009

Eligibility

Key inclusion criteria
1. Birth weight between 1000 and 1500 g
2. Being male
3. Being adequate for gestational age (birth weight greater than or equal to 10th percentile according to the Babson and Benda's chart updated)
4. Need for oxygen (O2) less than 40% within the first 72 hours

Participant type(s)
Patient

Age group
Neonate

Sex
Male

Target number of participants
9 patients per group (18 in total)

Key exclusion criteria
1. Starting parenteral nutrition (NPT) after the first 24 hours of life
2. Chromosomal abnormalities
3. Metabolic disease

4. Congenital infections (toxoplasmosis, rubella, cytomegalovirus, herpes simplex and human immunodeficiency virus [HIV] [TORCH])
5. Score of severity of clinical conditions at birth (CRIBB) greater than 4

Date of first enrolment
01/09/2008

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
Italy

Study participating centre
Via Commenda 12
Milano
Italy
20122

Sponsor information

Organisation
Institute of Paediatrics and Neonatology (Italy)

Sponsor details
University Medical School of Milan
Via Commenda 12
Milano
Italy
2012

Sponsor type
Research organisation

Website
http://www.mangiagalli.it

ROR
https://ror.org/00wjc7c48

Funder(s)

Funder type
Hospital/treatment centre

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