

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

Submission date 31/07/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/09/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/09/2008	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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 ($\alpha = 0.05$; 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(s)

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

Key secondary outcome(s)

Efficacy:

1. Body composition (assessed by means of deuterium and air plethysmography-Pea Pod) at birth, at 15 days of life and at 36 weeks of post-conceptual 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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

Male

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration