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Efficacy and safety of preterm formula supplemented with energy substrates for the nutrition of infants of very low birth weight

Submission date	Recruitment status	[ ] Prospectively registered
12/05/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/06/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/03/2011	Pregnancy and Childbirth	[ ] 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
40/2006

Study information

Scientific Title

Efficacy and safety of preterm formula addition with medium chain triglycerides or maltodextrins compared with milk formula without addition of energy substrates for nutrition of newborn very low birth weight: a randomised clinical trial

Acronym
MCT oil, vlbw

Study objectives
1. The preterm formula supplemented with medium chain triglyceride (MCT) oil to be administered to infants of very low birth weight is the most effective way to reach a weight of 1800 g in 16 days compared with patients fed the preterm formula supplemented with maltodextrin and the formula without added substrates
2. The preterm formula supplemented with MCT oil to be administered to infants of very low birth weight will be just as effective as the formula with maltodextrins and the formula without the addition of energy substrates to achieve a weight of 1800 g in 16 days based on clinical and biochemical parameters

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the National Institute of Pediatrics approved on the 24th October 2006 (ref: 40/2006)

Primary study design
Interventional

Study design
Phase III three-arm randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Very low birth weight

Interventions
Group 1 (n = 21): Preterm formula without supplements (control group)
Group 2 (n = 21): Preterm formula supplemented with maltodextrin (10 kcal/day). The amount of maltodextrin in the formula will be 10 kcal/day at start and this will be gradually increased each day to 10 kcal.
Group 3 (n = 21): Preterm formula supplemented with medium chain triglycerides. The amount of the medium chain triglycerides will be 10 kcal/day at start, and this will be increased each day to 10 kcal.

Total duration of interventions: minimum 21 days.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Maltodextrin, medium chain triglycerides

Primary outcome(s)
1. Number of days required to reach 1800 g in weight
2. Type of treatment administered
3. Weight
4. Height
5. Cephalic perimeter
6. Mid-arm circumference

Measured at 21 days.

Key secondary outcome(s)
1. Biochemical parameters: serum albumin, prealbumin, total protein, creatinine, blood-urea nitrogen (BUN), nitrogen balance
2. Security settings: abdominal perimeter, vomiting, stool consistency, temperature, blood in stools, serum glucose, calcium, phosphorus, magnesium, triglycerides

Measured at 21 days.

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Both male and female infants, aged less than 28 days
2. Hospitalised in the Intensive Care Unit (ICU) or Neonatal Intermediate Care Unit (NICU)
3. Weight less than 1500 g at birth
4. Fed exclusively via enteral route
5. Haemodynamic stability (arterio-venous 3 - 5)
6. Have not received prior formulas with added energy substrates
7. Signed informed consent by parents or guardians

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Patients suffering from inborn errors of metabolism in any variant or a disease in itself a negative influence on growth (congenital heart disease, kidney failure, genetic diseases)
2. Post-operative state greater than 72 hours

Date of first enrolment
10/01/2007

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Mexico

Study participating centre
Av. Coyoacan 1868 - 202
Mexico City
Mexico
03240

Sponsor information

Organisation
National Institute of Paediatrics (Instituto Nacional de Pediatria) (Mexico)

ROR
https://ror.org/05adj5455

Funder(s)

Funder type
Government

Funder Name
National Institute of Paediatrics (Instituto Nacional de Pediatria) (Mexico)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration