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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 12/05/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/06/2009	**Overall study status** Completed	
Last Edited 03/03/2011	**Condition category** 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
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)

Study design
Phase III three-arm 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
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 measure
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.

Secondary outcome measures
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.

Overall study start date
10/01/2007

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

Age group
Neonate

Sex
Both

Target number of participants
63

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)

Sponsor details
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Sponsor type
Government

Website
http://www.salud.gob.mx/unidades/pediatria/

ROR
https://ror.org/05adj5455

Funder(s)

Funder type
Government

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

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