

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	<input type="checkbox"/> Prospectively registered
Registration date 05/06/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/03/2011	Condition category Pregnancy and Childbirth	<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

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