

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

<b>Submission date</b> 12/05/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/06/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/03/2011	<b>Condition category</b> 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

**Contact name**  
Dr Alejandro Gonzalez

**Contact details**  
Av. Coyoacan 1868 - 202  
Col. Acacias  
Mexico City  
Mexico  
03240  
+52 (0)155 5524 1792  
pegasso.100@hotmail.com

## 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)

## **Study design**

Phase III three-arm randomised controlled trial

## **Primary study design**

Interventional

## **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 Pediatría) (Mexico)

### ROR

<https://ror.org/05adj5455>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute of Paediatrics (Instituto Nacional de Pediatría) (Mexico)

## Results and Publications

## **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration