

# Improvement of nutritional state by intradialytical parenteral nutrition in children treated with haemodialysis

**Submission date**

18/06/2010

**Recruitment status**

No longer recruiting

Prospectively registered

Protocol

**Registration date**

16/07/2010

**Overall study status**

Completed

Statistical analysis plan

Results

**Last Edited**

16/07/2010

**Condition category**

Nutritional, Metabolic, Endocrine

Individual participant data

Record updated in last year

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Mara Medeiros

**Contact details**

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Mexico  
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## Additional identifiers

**Protocol serial number**

HIM/2007/059

## Study information

**Scientific Title**

Improvement of nutritional state by intradialytical parenteral nutrition in children treated with haemodialysis: A prospective, randomised, controlled, crossover trial

**Acronym**

IDPN (Comparación de la mejoría nutricional por alimentación enteral vs. parenteral intradialítica en niños en programa de hemodiálisis)

**Study objectives**

Intradialytic parenteral nutrition (IDPN) is an effective intervention to improve the nutritional state of children treated with haemodialysis

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The local research ethics committee (Comisión de Etica Hospital Infantil de México Federico Gómez) approved on 29th of February 2008 (ref: HIM/2007/059)

**Study design**

Prospective randomised active controlled crossover group trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Malnutrition/Haemodialysis pediatric patients

**Interventions**

Malnourished children undergoing haemodialysis treatment (aged 6-17 years) will be included in the study. None will be receiving growth hormone. Each patient will receive a three month course of either Treatment A or Treatment B. For ethical reasons there is no washout period and patients will be switched to another three months of either Treatment A or B in order to complete the other arm of the crossover design.

1. Treatment A: Dietary supplementation providing a third daily calorie intake three times per week.

2. Treatment B. A three months course of intradialytical parenteral nutrition in every haemodialysis session (three times per week). The IDPN will provide a third of the required daily calorie intake, amino acids and lipids, will be adjusted by age and sex.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Improvement in ABN score (anthropometry-bioimpedance analysis-nutrition) at 3 and 6 months

**Key secondary outcome(s)**

1. improvement in inflammation biomarkers (IL-6, TNF alpha)
1. Peripheral blood gene expression of IL6, TNF alpha, IFN gamma, 18s-rRNA at baseline, 3 and 6 months
2. Adverse events to nutritional intervention

**Completion date**

28/05/2011

## Eligibility

**Key inclusion criteria**

1. Patients aged 6-17 years
2. Anthropometry-BIA nutrition (ABN) Score <10.33
3. Functional haemodialysis vascular access
4. Expected time in haemodialysis at least 6 months
5. No evidence of active infection
6. Informed consent/assent properly signed

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 years

**Upper age limit**

17 years

**Sex**

All

**Key exclusion criteria**

1. Hepatic dysfunction
2. Congenital anomalies in amino acid metabolism
3. Use of immunosuppressive drugs
4. Treatment with growth hormone

**Date of first enrolment**

28/05/2008

**Date of final enrolment**

28/05/2011

## Locations

## Countries of recruitment

Mexico

## Study participating centre

**Dr. Marquez 162**

Mexico City

Mexico

06720

## Sponsor information

### Organisation

Baxter Healthcare Corporation (USA)

### ROR

<https://ror.org/02d6ew870>

## Funder(s)

### Funder type

Industry

### Funder Name

Baxter Healthcare Corporation (USA) - Renal Discoveries BAXTER Extramural grant

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration