

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

Dr. Marquez 162
Colonia Doctores
Mexico City
Mexico
06720

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