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Efficacy of oral intra-dialysis supplement in haemodialysis patients with malnutrition

Submission date	Recruitment status	[ ] Prospectively registered
06/11/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/11/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/11/2007	Nutritional, Metabolic, Endocrine	[ ] 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

Protocol serial number
06/178

Study information

Scientific Title

Study objectives

Nutritional support in the form of oral supplement during the sessions of haemodilaysis improves the nutritional status of the patients, increases the oral food intake, improves the functional situation and quality of life and reduces the morbidity and mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethical Committee of Clinical Investigation of the Hospital Clinico San Carlos on the 24th January 2007 (ref: 1.2/07). Signed by secretary of the committee Dr. M. Garcia Arenillas.

Study design
Randomised controlled single-blinded trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Specific oral supplement formula for patients on haemodialysis (Nepro) plus dietetic consultation for the case group, versus only dietetic consultation for the control group.
The formula is Nepro, a product of Abbott laboratory. Dosage is 236 ml in each session of haemodialysis, providing 472 kcal and 7 g of protein per 100 ml.

Duration of intervention: 6 months

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The following data will be collected at the beginning of the study (basal), and at three and six months (final):
1. Serum albumin, measured by blood analysis
2. Prealbumin, measured by blood analysis

Key secondary outcome(s))
Collected at the beginning of the study (basal), collected at the beginning of the study (basal), and at three and six months (final):
1. Prevalence of malnutrition
2. Anthropometric nutritional parameters
3. Analytical nutritional parameters

4. Body composition (collected at the beginning of the study [basal] and at the sixth month [final] only)
5. Quality of life
6. Functional scale
7. Appetite
8. Oral food intake. Later on this information will be passed through a special program in order to calculate the total caloric intake and food composition (protein, carbohydrates and fat including saturated, mono- and poly-unsaturated fat)
9. Hospital admissions (collected as and when these events happen)
10. Mortality (collected as and when these events happen)
11. Morbidity and mortality rate (collected as and when these events happen)

Measurements taken to assess these outcomes will include:
1. Anthropometric measures: dry body weight, Body Mass Index (BMI), Brachial Muscle Circumference (BMC), triceps skin fold
2. Blood tests: Complete Blood Count (CBC), urea prior and post dialysis, creatinine, electrolytes, lipid profile, serum iron, ferritin, vitamin B12, folic acid, Parathyroid Hormone (PTH), calcium, phosphate, vitamin D3, transferrin, albumin, prealbumin, bicarbonate (HCO3) prior and post dialysis, insulin, fasting blood sugar, Homeostasis Model Assessment (HOMA) index, C-Reactive Protein (CRP)
3. Body composition: electrical Bioimpedance Analysis (BIA) monofrequency
4. Nutritional assessment: SGA and MIS
5. Questionnaires: charlson index, karnofsky scales (evaluated by interviewing each patient and by checking his medical history report at the beginning of the study, third month and sixth month), 36-item Short Form health survey (SF-36) and 8-item Council on Nutrition Appetite Questionnaire (CNAQ)
6. Dietary recall (48 hours): day of dialysis and day off will be collected from patients interview

Completion date
15/05/2008

Eligibility

Key inclusion criteria
1. Patients over 18 years old
2. Maintained haemodialysis (at least 6 months on dialysis)
3. Malnutrition criteria (Subjective Global Assessment [SGA] grade B or C or Malnutrition Inflammation Score [MIS] score greater than 8) and at least two altered analytical parameters (albumin less than 3.7 g/dl, prealbumin less than 30 g/l, total cholesterol less than 200 mg/dL with C-Reactive Protein [CRP] within normal range)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Key exclusion criteria
1. Lack of signed consent
2. Difficulty in understanding Spanish language
3. Patients diagnosed of cancer except skin cancer
4. Patients went through surgical operation in the last three months
5. Patients with Dementia or Alzheimer disease

Date of first enrolment
15/11/2007

Date of final enrolment
15/05/2008

Locations

Countries of recruitment
Spain

Study participating centre
Avenida Marques de Corbera 6, 6d
Madrid
Spain
28017

Sponsor information

Organisation
Foundation of Metabolic Studies (Fundacion de estudios metabolicos) (Spain)

Funder(s)

Funder type
Research organisation

Funder Name
Foundation of Metabolic Studies (Fundacion de estudios metabolicos) (Spain) - in cooperation with the Hospital Clinco San Carlos (Spain), Department of Endocrinology and Nutrition

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration