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Protein metabolism in chronic kidney disease

Submission date	Recruitment status	[_] Prospectively registered
18/01/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/02/2013	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/06/2017	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Protein-energy wasting (PEW) is common in patients with chronic kidney disease. It is a condition where the body has decreased stores of protein and energy and is associated with an increased risk of death. The aim of this study is to investigate the response to a low protein diet and a keto /amino acid supplemented very low protein diet in patients with chronic kidney disease.

Who can participate?
Patients aged 18 to 79 with chronic kidney disease

What does the study involve?
The study is composed of two different studies. In study A participants eat a usual-protein diet followed by a low-protein diet to find out how skeletal muscle protein turnover adapts. Study B consists of four six-week periods: the enrollment period, a low-protein diet period, a keto/amino acid supplemented very low protein diet period, and another low-protein diet period. Protein turnover (both whole body and muscle) is measured at the start of the study and at the end of each six-week period.

What are the possible benefits and risks of participating?
The study provides new information on how the body adapts to a low protein diet, and may be helpful for the understanding of their nutritional safety. The study involves the use of stable isotopes of naturally occurring amino acids, a procedure which is not harmful. The possible risks of measuring muscle protein turnover are those related to cannulation (where a tube is inserted into a blood vessel).

Where is the study run from?
Università degli studi di Genova (Italy)

When is the study starting and how long is it expected to run for?
January 2013 to June 2014

Who is funding the study?
Fresenius Kabi (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effects of a low protein diet and of a keto/amino acid supplemented very low protein diet on muscle protein metabolism and myostatin in patients with chronic kidney disease

Acronym
PMCKD

Study objectives
The hypothesis is that the use of keto/amino acid supplements may partially or totally reverse the abnormal amino acid metabolism thus counteracting the uremia-related muscle cell loss and catabolic events.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRCCS Azienda Ospedaliera Universitaria San Martino- IST Istituto Nazionale per la Ricerca sul Cancro, 13/04/2012, ref: 7/2012

Study design
Non-randomized prospective self-controlled crossover trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic kidney disease

Interventions
Low protein diet or supplemented very low protein dieT (vLPD)

The research protocol is composed of two different studies:

Study A: to determine how skeletal muscle protein metabolism adapt to a low protein diet, forearm protein turnover will be evaluated in the same CKD patients assigned to a usual-protein diet (1.1 g/kg/day, 30-35 kcalday), followed by a low-protein diet (LPD) (0.8 g/kg, followed by 0.55 g/kg, 30-35 kcal/Kg/day). Each time period of study is 6 weeks, with total length of period of time during which patient will be followed up of 18-24 weeks. To determine the muscle responses to a supplemented vLPD (0,45 g/kg, supplemented with 0.1 g/kg Ketosteril, 30-35 kcal /Kg/day)

Study B: protein turnover (both whole body and muscle), muscle and plasma myostatin, muscle apoptosis, muscle proteolytic-related genes and intracellular insulin signaling, will be studied in a prospective cross-over trial with CKD patients serving as their own controls. Study B consists of four six-week consecutive periods: the enrollment period, the baseline (LPD) period, the treatment period (supplemented protein-restricted, vLPD) and the wash-out LPD period .

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Protein metabolism measured at baseline and at the end of each six-week experimental period

Key secondary outcome(s))
Serum/muscle myostatin measured at baseline and at the end of each six-week experimental period

Completion date
06/06/2014

Eligibility

Key inclusion criteria
1. Aged 18-79, both males and females
2. Non-diabetic CKD (Stages 4-5, estimated glomerular filtration rate [eGFR] 12-25 ml/min)
3. Compliance to treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
79 years

Sex
All

Key exclusion criteria
1. Evidence of congestive heart failure
2. Incapable of following study requirements to control diet
3. A recent myocardial infarction
4. Pregnancy
5. Unstable renal function
6. Recent (<3 months) infection history
7. Clinical evidence of gastrointestinal or liver diseases
8. Alcoholism
9. Drug abuse
10. Final diagnosis of malignancy

Date of first enrolment
10/01/2013

Date of final enrolment
06/06/2014

Locations

Countries of recruitment
Italy

Study participating centre
Viale Benedetto xv
Genoa
Italy
16132

Sponsor information

Organisation
Fresenius Kabi Deutschland GmbH (Germany)

ROR
https://ror.org/01v376g59

Funder(s)

Funder type
Industry

Funder Name
Fresenius Kabi (Germany) - Ketosteril Award

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration