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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?
Prof. Giacomo Garibotto
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Giacomo Garibotto

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Non randomised study

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

## 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 measure

Protein metabolism measured at baseline and at the end of each six-week experimental period

### Secondary outcome measures
Serum/muscle myostatin measured at baseline and at the end of each six-week experimental period

### Overall study start date
10/01/2013

### 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

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
79 Years

### Sex
Both

### Target number of participants
20

### 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
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16132

# Sponsor information

**Organisation**
Fresenius Kabi Deutschland GmbH (Germany)

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**Sponsor type**
Industry

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http://www.fresenius-kabi.com/

**ROR**
https://ror.org/01v376g59

# Funder(s)

**Funder type**
Industry

**Funder Name**
Fresenius Kabi (Germany) - Ketosteril Award

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

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

**IPD sharing plan summary**
Not provided at time of registration