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Efficacy of the essential amino acids and keto-Analogues on the CKD progression rate

Submission date	Recruitment status
23/04/2016	No longer recruiting
Registration date	**Overall study status**
06/05/2016	Completed
Last Edited	**Condition category**
23/02/2018	Urological and Genital Diseases

✓ Retrospectively registered
? Protocol not yet added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
Background and study aims
Chronic kidney disease (CKD) is a long term medical condition in which the kidneys do not work as well as they should. Symptoms don't normally occur until the condition is at an advanced stage but can be detected earlier via blood and urine tests. Symptoms include feeling tired, swollen hands, feet or ankles, feeling short of breath, feeling nauseous and passing blood in the urine. The rate at which CKD progresses depends on numerous factors and can be delayed by nephroprotective therapy (treatment to protect the kidneys), in particular – by nutrition therapy. Some studies confirmed that a Very Low Protein Diet (VLPD) supplemented by essential amino-acids and keto-analogues (EAA/KAA) can slow the progression of CKD. Regimens with less than 0.6 g/kg/day protein intake are often difficult to implement, unless 'non-proteic' (commercially available) carbohydrates are applied to ensure that enough calories are eaten, however this products are not easily available everywhere for every patient and different approaches may be acceptable. The aim of his study is to see whether a low protein diet (LPD) supplemented by essential amino acids and keto-analogues have help delay the progression of CKD.

Who can participate?
Adults with chronic kidney disease showing a moderate decline in kidney function.

What does the study involve?
All participants are offered dietary counselling. LPD is recommended for those patients that are at high risk for CKD progression. Patients that stick to a LPD, low phosphate diet may also be considered for additional restriction of dietary protein and essential amino acids/keto-analogue supplements. The effectiveness of the treatment is determined though 10 regular visits to the study centre where the participants GFR decline rate(rate of kidney function decline) is calculated. Results are compared with those from a group of participants matched by gender, age, diagnosis and CKD stage) selected from the city Registry.

What are the possible benefits and risks of participating?
The expected benefit is a slowing down of the progression of CKD and delaying the necessity or renal replacement therapy. The possible risk of participating is the development of protein-

energy wasting (PEW). The patients are examined for PEW signs and symptoms on regular base to avoid this risk.

Where is the study run from?
City Nephrology Center, Saint Petersburg (Russia)

When is study starting and how long is it expected to run for?
September 2013 to September 2016

Who is funding the study?
City Nephrology Center, Saint Petersburg (Russia)

Who is the main contact?
Mr Alexander Zemchenkov
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
NC-2-2013

Study information

Scientific Title
Efficacy of the essential amino acids and keto-analogues on the CKD progression rate in real practice in Russia - City Nephrology Registry Data for Outpatient Clinic

Study hypothesis
Low protein diet supplemented by essential amino acids and keto-Analogues can retard CKD progression

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee (City Mariinsky hospital, Saint Petersburg), 12/02/2013, ref: #40

Study design
Single center observational study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Other

Study type(s)
Treatment

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

Condition
Chronic kidney disease, stages 3B-5

Interventions
All patients with CKD Stage 3–5, referred to city nephrology center, are offered dietary counseling by experienced nephrologist. LPD is routinely recommended to all patients at high risk for CKD progression after evaluation the CKD stage, GFR decline rate and excluding the symptoms and signs of protein-energy wasting based on physician's judgment and labs: albumin <3.8 or <3.5 g/dl for diabetics, phosphate < 0.8 mmol/l; anthropometric data. For patients who demonstrated treatment compliance to LPD, low-phosphate diet, nephroprotective therapy (iACE or ARB), and have moderate to severe proteinuria (>1.0 g/day), the additional restriction of dietary protein, supplemented by EAA/KAA may be considered. Patients are provided with EAA /KAA (prescribed dose - one pill per 5 kg body weight) by the budgetary funded drugstore.

The total duration of study is determined by 10 regular visits to calculate the scope of eGFR decrease during two sequential 5-visits period to compare it as a measure of intervention effectiveness. The frequency of regular visits depends on CKD stage.

As a control group, the equal number of patients are selected randomly from three-time larger group matched by gender, age, diagnosis, proteinuria and CKD stage to treatment group. The matching provide the similar feature for both groups (please, see enclosed table). The matching process represented by repeated excluding of small groups with the most outstanding features comparing treatment group up to reaching similarity.

Intervention Type
Supplement

Primary outcome measure
The change in eGFR decline scope (evaluated during two periods of five consequtive outpatient visit during the LPD (<0.6 g/kg/day) supplemented with EAA/KAA compared with that for patients with LPD (0.6-0.8 g/kg/day). The eGFR decline scope is calculated for every patient for both periods as a regression coefficient in 5 pairs: eGFR - visit date (ml/min/ per year). The frequency of the visits is predetermined according CKD stage: quarterly for CKD3, bimonthly for CKD4 and monthly for CKD5.

Secondary outcome measures
Change in quality of life parameters (evaluated by KDQoL questionnaire)

Overall study start date
01/09/2013

Overall study end date
01/09/2016

Eligibility

Participant inclusion criteria
1. Confirmed moderate GFR decline rate
2. Patient`s compliance to diet and pharmacological therapy
3. Prolonged history of regular EAA/KAA therapy according to the data from special database, recording patient's` visits to drugstore for EAA/KAA supplied by budgetary funded source (≥ 10 consecutive visits with pre-defined for each CKD stage frequency).

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
90

Participant exclusion criteria
1. Patients with very low life expectancy
2. Patients with rapid CKD progression (more than 10 ml/min/1.73m2 per year)

Recruitment start date
01/03/2014

Recruitment end date
01/10/2014

Locations

Countries of recruitment
Russian Federation

Study participating centre
City Nephrology center
191104
56, Liteiny pr.
St-Petersburg
Russian Federation
191104

Sponsor information

Organisation
St-Petersburg City Nephrology center

Sponsor details
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St. Petersburg City Nephrology center

Results and Publications

Publication and dissemination plan
Article with study results "Efficacy of the Essential Amino Acids and Keto-Analogues on the CKD Progression Rate in Real Practice in Russia - City Nephrology Registry Data for Outpatient Clinic." is submitted to BioMedCentral - Nephrology

Intention to publish date
01/09/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/07/2016		Yes	No