

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

Submission date 23/04/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/05/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 23/02/2018	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

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-protein' (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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 objectives

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

Health condition(s) or problem(s) studied

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 slope 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 slope (evaluated during two periods of five consecutive 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 slope 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

Completion date

01/09/2016

Eligibility

Key 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

Key exclusion criteria

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

Date of first enrolment

01/03/2014

Date of final enrolment

01/10/2014

Locations**Countries of recruitment**

Russian Federation

Study participating centre

City Nephrology center

191104

56, Liteiny pr.

St-Petersburg

Russian Federation

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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