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Exploring the effect of the supplement AB070597 in humans with declining kidney function

Submission date	Recruitment status	[_] Prospectively registered
22/07/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/08/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/12/2020	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Creatinine is a chemical waste product that's produced as a result of muscle movement and to a smaller extent by eating meat. Healthy kidneys filter creatinine and other waste products from your blood. The filtered waste products leave your body in your urine. In patients with kidney disease, as the disease progresses, the level of creatinine in the blood rises.

Glomerular filtration rate is another way to determine the extent of kidney disease and test the level of kidney function.

Based on a previous literature review, it was thought that supplementation with certain amino acids may have a role in improving renal (kidney) function as they have been shown to decrease blood-serum creatinine concentration and increase the glomerular filtration rate.

The trial aims to find whether oral supplementation with a specific amino acid/peptide complex will stabilize or improve the estimated glomerular filtration rate in humans with declining kidney function and if there is rationale for conducting a future randomized controlled trial with larger sample size.

Who can participate?
Non-diabetic white males aged 63 to 80 years under concurrent medical care in the United States, with chronic kidney disease (CKD) or an increased fall in kidney function over the previous 24 months.

What does the study involve?
Participants will take the supplement AB070597 (via mouth) daily for 10 months. They will give blood samples monthly during this period.

What are the possible benefits and risks of participating?
AB070597 supplementation may stabilize or improve renal function.

There are no known risks from taking dietary supplement AB070597.
Risks from blood collection include potential pain from the needle stick, and/or bruising.

Where is the study run from?
Quest Diagnostics (USA)

When is the study starting and how long is it expected to run for?
From April 2016 to May 2017

Who is funding the study?
John T Fulton Trust (USA)

Who is the main contact?
Dr James Archer
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AB070597-5H

Study information

Scientific Title
Exploratory-data and statistical analyses of AB070597, an amino acid and peptide complex, on blood-serum creatinine concentration and estimated glomerular filtration rate: a non-randomized pilot trial of five humans with declining renal-function

Study objectives
Oral supplementation with a specific amino acid/peptide complex will stabilize or improve the estimated glomerular filtration rate in humans with chronologically declining renal function

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/18/2016, Pearl IRB (29 E McCarty Street, Suite 100, Indianapolis, IN 46225 USA; +1 317-602-6104; gparker@pearlpathways.com), ref: 16-BIOS-101

Study design
Single-center open-ended longitudinal non-randomized, non-controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Dr. James Archer (photoresearch@sbcglobal.net) to request a patient information sheet

Health condition(s) or problem(s) studied
Declining renal function in chronic kidney disease

Interventions
The intervention is oral administration of a daily dose of a specific amino acid/peptide complex. All participants are asked to follow the dosing schedule of six 1000 mg capsules, taken twice daily. Each capsule contains: 83 mg L-arginine, 167 mg glycine, 167 mg L-glutamine, 83 mg L-histidine, 167 mg L-aspartic acid, 167 mg L-glutamic acid, 167 mg L-carnosine.

Treatment continued for 12 consecutive months, with blood-serum creatinine concentration measured at 1-month intervals.

Intervention Type
Supplement

Primary outcome measure

1. Estimated glomerular filtration rate (eGFR) calculated from participant age and blood-serum creatinine concentration at baseline, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12 months
2. Individual eGFR median-rate-of-change per unit time compared to eGFR medium-rate-of-change per unit time of 2870 chronic kidney disease participants in a study by Tsai CW, et al. (2017) using non-parametric one-sample Wilcoxon signed-rank test

Secondary outcome measures
1. Estimated glomerular filtration rate measured by blood-serum creatinine and age at baseline, 12, 34, and 36 weeks

Overall study start date
01/11/2016

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. Aged 63 to 80 years
2. White
3. Male
4. Under concurrent medical care in the United States
5. Chronic kidney disease (CKD) or an estimated glomerular filtration rate (eGFR) decline rate of ≥4 ml/min/1.73 m^2 over the previous 24 months
6. History of increasing blood-serum creatinine from CKD or as a consequence of aging

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
5

Total final enrolment
5

Key exclusion criteria
1. Concurrent or suspected comorbidities unrelated to CKD
2. Diabetic

Date of first enrolment
30/11/2016

Date of final enrolment

Locations

Countries of recruitment
United States of America

Study participating centre
Quest Diagnostics
555 E. Tachevah Dr.
Ste. 102 W
Palm Springs
California
United States of America
92262

Study participating centre
Davita Pomona Dialysis
2111 N. Garey Ave.
Pomona
California
United States of America
91767

Study participating centre
Quest Diagnostics
23441 Madison Street, Suite 300
Torrance
California
United States of America
90505

Study participating centre
Quest Diagnostics
11525 Brookshire Avenue, Suite 401
Downey
California
United States of America
90241

Study participating centre

Quest Diagnostics
8401 Fallbrook Ave.
West Hills
California
United States of America
91304

Sponsor information

Organisation
Whitsell Innovations

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Charity

Funder Name
John T Fulton Trust

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/11/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study are/will be available to reasonable requests from the Applied Research Laboratory. Contact Dr. James Archer at photoresearch@sbcglobal.net.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/11/2020	04/12/2020	Yes	No