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Influence of a specific diet on chronic kidney disease progression

Submission date
22/12/2021

Recruitment status
No longer recruiting

Registration date
04/01/2022

Overall study status
Completed

Last Edited
20/12/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Chronic kidney disease (CKD) is a long-term condition where the kidneys don't work as well as they should.
The aim of our study is to understand the interaction between the nutritional, inflammatory, and oxidative status and the gut microbiota composition in CKD patients. The project also aims at generating new knowledge on the role played by diet in CKD and at translating emerging evidence in secondary prevention interventions to limit the worsening of CKD status and to improve patients' nutritional status.

Who can participate?
Thirty patients with CKD (stage 3b-5, not on haemodialysis treatment) and twenty healthy subjects will be recruited at the San Paolo Hospital, Unit of Nephrology and Dialysis.

What does the study involve?
CKD patients receive curcumin (Meriva® 500 mg/tablet twice in a day) for 3 or 6 months. Meriva® was supplied by INDENA S.p.A. (Milan, Italy) as a food-grade lecithin formulation of curcumin in 500mg film-coated tablets, containing a standardized amount of 100 mg highly bioavailable curcuminoids. At baseline (T0), after 3 months (T1) and 6 months (T2) of Meriva® supplementation, we collect: patients' clinical parameters, anthropometric and body composition measures, dietary habits, stool and blood samples.

What are the possible benefits and risks of participating?
Meriva® is a safe curcumin supplement currently on the market. The recruited patients will be followed from a nutritional point of view, which can bring health benefits. The study involves no health risks.

Where is the study run from?
San Paolo Hospital - Milan. University of Milan (Italy).

When is the study starting and how long is it expected to run for?
January 2017 to October 2021

Who is funding the study?
University of Milan (Italy).

Who is the main contact?
Dr Francesca Pivari, francesca.pivari@unimi.it

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MRC2017/ST/035

Study information

Scientific Title
Influence of a specific diet on the intestinal microbiota, malnutrition, inflammation and oxidation in chronic kidney disease

Acronym
NutriCKD

Study objectives

The purpose of the study is to investigate the anti-inflammatory and antioxidant action of specific foods and to understand their interaction with the composition of the intestinal microbiota in patients with chronic kidney disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/01/2017, Ethics Committee Milano Area 1 (ASST Fatebenefratelli Sacco, Via G.B Grassi, 74. 20157 - Milano, Italy; no telephone number provided; comitato.etico@asst-fbf-sacco.it), ref. Protocollo MRC 2017/ST/035.

Study design
Interventional non-randomized

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Increase the quality of life of patients with chronic kidney disease.

Interventions
To ameliorate the quality of life in chronic kidney disease (CKD) subjects, the use of dietary supplements has increased over time. Among those, curcumin has demonstrated significant in vitro anti-inflammatory properties. In this pilot study, 24 CKD patients and 20 healthy volunteers were recruited. CKD patients followed nutritional counselling and were supplemented with curcumin (1g/day Meriva®) for six months. Different parameters were evaluated at baseline and after 3-6 months: uremic toxins, metagenomic of gut microbiota, nutritional, inflammatory and oxidative status.
Healthy volunteers: completed a 3-days food diary to record their eating habits; bioimpedance analysis; collected stool samples to analyze gut microbiota composition.

Intervention Type
Supplement

Primary outcome(s)
1. Nutritional, inflammatory and oxidative status measured using 3-days food diary, bioimpedance, ELISA immunological test for eight cytokines/chemokines on plasma and lipoperoxidation levels on plasma (TBARS assay) at baseline, after 3 months and after 6 months
2. CKD progression measured using glomerular filtration rate (eGFR, CKD-EPI formula) at baseline, after 3 months and after 6 months

Key secondary outcome(s))
1. Gut microbiota measured using Next Generation Sequencing (Ion 16S Metagenomics Kit) on DNA extracted from stool samples at baseline, after 3 months and after 6 months
2. Uremic toxins measured using mass spectrometry (LC-MS/MS) at baseline, after 3 months and after 6 months

Completion date
01/10/2021

Eligibility

Key inclusion criteria
Patients:
1. CKD from stage 3a to 4 (defined according to the GFR values of the KDOQI guide-lines), not being on hemodialysis treatment
2. Age ≥ 18 years
3. Absence of: chronic infections, active neoplasm, vasculitis, autoimmune or acute inflammatory diseases, gastro-intestinal pathologies, dementia, steroid therapies, and pregnancy

Healthy volunteers:
1. Age and sex-matched with CKD group
2. Absence of CKD or other kidney-related pathologies

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
24

Key exclusion criteria
All groups:
Presence of: chronic infections, active neoplasm, vasculitis, autoimmune or acute inflammatory diseases, gastro-intestinal pathologies, dementia, steroid therapies, and pregnancy.

Date of first enrolment
01/10/2018

Date of final enrolment
01/10/2019

Locations

Countries of recruitment

Italy

Study participating centre
San Paolo Hospital - Milan
Via A. di Rudinì, 8
Milan
Italy
20142

Sponsor information

Organisation
University of Milan

ROR
https://ror.org/00wjc7c48

Funder(s)

Funder type
University/education

Funder Name
Università degli Studi di Milano

Alternative Name(s)
Universitas Studiorum Mediolanensis, University of Milan, La Statale, UniMi

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan

Available on request. (francesca.pivari@unimi.it)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/01/2022	20/12/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes