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Testing a synbiotic functional drink to support kidney and metabolic health in adults with diabetic kidney disease

Submission date
01/09/2026

Recruitment status
Not yet recruiting

Registration date
14/09/2026

Overall study status
Ongoing

Last Edited
09/09/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Diabetes can gradually damage the kidneys. This is known as diabetic kidney disease or diabetic nephropathy. It can lead to chronic kidney disease and, in some people, eventually to dialysis. Researchers are increasingly interested in the relationship between the gut microbiome, inflammation, nitrogen-containing waste products and kidney function. REVITAL is a fermented functional drink containing inulin and plant-derived ingredients. The aim of this pilot study is to find out whether taking REVITAL for 10 weeks is safe and whether it produces early favourable changes in kidney, glucose, digestive, inflammatory and nutritional markers compared with inulin alone or placebo.

Who can participate?
Patients aged 18 years or older with diabetes and diabetic kidney disease

What does the study involve?
Participants will be randomly assigned to one of three groups. One group will receive placebo, one will receive inulin and one will receive REVITAL. All products will be taken as 15 ml by mouth every 12 hours for 10 weeks, with the active contents depending on the assigned group. Participants and key members of the research team will not know the assigned group during the study. Blood and urine tests will assess glucose and kidney-related markers. Blood counts, digestive symptoms, body measurements and nutritional status will also be assessed. The main study visits are at baseline, week 5 and week 10. Participants will continue their usual medical care. An optional stool sample may be used for an exploratory microbiome analysis if funding and collaboration with INMEGEN are available and the participant gives separate consent.

What are the possible benefits and risks of participating?
Participants may not receive a direct health benefit. The study may help determine whether REVITAL or inulin is associated with useful early changes in metabolic, kidney, digestive or nutritional health. Possible discomforts include pain or bruising from blood sampling, temporary

digestive symptoms such as gas, bloating, nausea, diarrhoea or changes in bowel habits, and intolerance or allergy to a study ingredient. Adherence and adverse events will be monitored throughout the 10-week study.

Where is the study run from?
Universidad Autónoma de Aguascalientes (Mexico)

When is the study starting and how long is it expected to run for?
October 2026 to July 2027

Who is funding the study?
VTL+CARE, S.A.P.I. de C.V. is providing the financial support for the study. The funds are administered through the Universidad Autónoma de Aguascalientes under the institutional agreement and project management procedures.

Who is the main contact?
Dr Adán Israel Rodríguez Hernández, israel.rodriguez@edu.uaa.mx

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Internal institutional reference assigned to the study by the researcher's home university in Mexico
C. No. SP_068_26 | REVITAL-UAA-2026-08-27

Study information

Scientific Title
A randomized triple-blind three-arm pilot trial of a synbiotic functional beverage versus inulin and placebo on renal, glycaemic, inflammatory, gastrointestinal and nutritional outcomes in adults with diabetic kidney disease

Acronym
REVITAL-DKD

Study objectives
The aim of this pilot study is to find out whether taking REVITAL for 10 weeks is safe and whether it produces early favourable changes in kidney, glucose, digestive, inflammatory and nutritional markers compared with inulin alone or placebo.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/08/2026, Bioethics Committee of the Autonomous University of Aguascalientes (Universidad Autónoma de Aguascalientes, Av. Universidad #940, Ciudad Universitaria, C.P., Aguascalientes, 20100, Mexico; +52 (0)449 910 7400; aquinta@correo.uaa.mx), ref: COB-UAA/25/2026

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Prevention, Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Diabetic kidney disease (diabetic nephropathy)

Interventions
Participants will be randomized 1:1:1 before recruitment using a numerical random sequence under the custody of Dra. Paloma Lucía Guerra Ávila. Group 1 (placebo) will receive 15 ml orally every 12 hours for 10 weeks, preserving the daily placebo composition defined in the protocol. Group 2 (inulin) will receive 3.5 g inulin in 15 ml orally every 12 hours (7 g/day) for 10 weeks. Group 3 (REVITAL) will receive 15 ml of REVITAL orally every 12 hours (30 ml/day) for 10 weeks. Products will be supplied in coded containers and participants, clinical outcome assessors and data analysts will remain blinded. Assessments will be performed at baseline, week 5 and week 10. Usual medical care will continue throughout the study.

Intervention Type
Supplement

Primary outcome(s)
1. HbA1c (%) measured using a turbidimetric immunoassay at baseline and week 10

2. Fasting blood glucose (mg/dL) measured using the standard glucose oxidase method, based on spectrophotometric detection of absorbance changes in an automated clinical chemistry analyzer with integrated software, at baseline, week 5, and week 10

3. Serum creatinine (mg/dL) measured using an enzymatic method with spectrophotometric colorimetric detection in an automated clinical chemistry analyzer with integrated software, at baseline, week 5, and week 10

4. Serum urea and blood urea nitrogen (BUN, mg/dL) measured using the urease-glutamate dehydrogenase enzymatic method, based on the ultraviolet absorbance decrease caused by NADH consumption, in an automated clinical chemistry analyzer with integrated software, at baseline, week 5, and week 10

5. Urinary albumin-to-creatinine ratio (ACR, mg/g) measured using a urine sample. Albumin is quantified using an immunoturbidimetric method, and urinary creatinine is measured enzymatically in an automated clinical chemistry analyzer with integrated software. The ACR is calculated by dividing urinary albumin concentration by urinary creatinine concentration and expressing the result as milligrams of albumin per gram of creatinine (mg/g). Measured at baseline and week 10

Key secondary outcome(s)
1. Complete blood count and erythrocyte indices (haemoglobin, haematocrit, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration and red cell distribution width) measured using flow cytometry at baseline and week 10
2. Absolute lymphocyte count and neutrophil-to-lymphocyte ratio measured using the complete blood count at baseline and week 10.
3. Functional gastrointestinal symptoms measured using a structured questionnaire based on Rome IV criteria at baseline and week 10.
4. Nutritional status and anthropometry, including body weight measured using a calibrated digital scale; BMI calculated from body weight and height; mid-upper arm circumference measured with a non-stretchable anthropometric tape; triceps skinfold measured using a skinfold caliper; and arm muscle area calculated from MUAC and triceps skinfold, at baseline and week 10.
5. Adherence and adverse events are measured as follows: adherence is assessed using structured questionnaires or interviews, along with protocol compliance verification to ensure that participants follow study instructions (diet, activity, measurements, and biochemical checks). Adverse events are monitored through interviews, physical examinations, laboratory evaluations, and vital signs throughout the 10-week intervention.
6. Exploratory faecal microbiome taxonomic diversity/abundance, if resources and collaboration with INMEGEN are available and separate consent is provided measured using microbiome sequencing at the end of the 10-week intervention.

Completion date
30/07/2027

Eligibility

Key inclusion criteria
1. Age 18 years or older
2. Diabetes mellitus with diabetic kidney disease/chronic kidney disease Kidney Disease Outcomes Quality Initiative (K/DOQI) stage 2, 3a, 3b or 4, clinically stable and with documented chronicity
3. HbA1c ≥6.5% as defined in the protocol
4. Stable medical and nutritional treatment whenever clinically possible
5. Able to provide informed consent and attend follow-up visits
6. Agreement not to initiate new commercial probiotic/prebiotic products during the study unless medically indicated

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. K/DOQI stage 5 (eGFR <15 ml/min/1.73 m²), current renal replacement therapy, immediate indication for dialysis or renal transplant
2. Pregnancy or breastfeeding
3. Severe acute infection, decompensated liver disease, active cancer or another condition that substantially increases risk
4. Systemic antibiotic use during the previous 4 weeks
5. Allergy or clinically relevant intolerance to components of the study products
6. Participation in another clinical trial within the previous 3 months
7. Major therapeutic changes or clinical deterioration that, in the investigator's judgement, make continued participation unsafe

Date of first enrolment
01/10/2026

Date of final enrolment
15/12/2026

Locations

Countries of recruitment
Mexico

Sponsor information

Organisation
Universidad Autónoma de Aguascalientes (UAA), Av. Universidad #940, Ciudad Universitaria, C.P. 20100, Aguascalientes, Ags., Mexico.

Funder(s)

Funder type

Funder Name
VTL+CARE, S.A.P.I. de C.V. (RFC VTL260122532). Funds are administered through the UAA institutional agreement/project management process.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		29/08/2026	02/09/2026	No	No