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Calcium dobesilate in diabetic nephropathy and chronic venous insufficiency (pilot study)

Submission date
15/08/2026

Recruitment status
No longer recruiting

Registration date
20/08/2026

Overall study status
Completed

Last Edited
20/08/2026

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
People with type 2 diabetes often develop kidney damage (diabetic nephropathy) and poor vein circulation in their legs (chronic venous insufficiency) at the same time. Both conditions share a common underlying problem: damage to the inner lining of small blood vessels. Calcium dobesilate is an existing medication that targets these small blood vessels and has been used for decades in diabetic eye disease and leg vein problems, but no study has looked at whether it can improve kidney and vein outcomes together in patients who have both conditions. This study aimed to find out whether adding calcium dobesilate to patients' usual treatment was associated with a reduction in protein leaking into the urine (a marker of kidney damage), an improvement in the severity of leg vein disease, and stable kidney function over a 3-month treatment period followed by a 1-month observation period after stopping the drug.

Who can participate?
Adults aged 20 to 80 years with type 2 diabetes who have protein in their urine (albumin-to-creatinine ratio of 30 mg/g or above), moderately reduced kidney function (eGFR between 30 and 90 ml/min/1.73 m²), and visible signs of chronic vein disease in their legs graded as CEAP class C3 or higher (meaning at least leg swelling, and possibly skin changes or ulcers). Patients must have been on stable diabetes medication for at least 3 months, with HbA1c between 6.5% and 9%. People taking SGLT2 inhibitors or GLP-1 receptor agonists are not eligible, nor are those with very advanced kidney failure, poorly controlled blood pressure, type 1 diabetes, pregnancy, known allergy to calcium dobesilate, active cancer, or immunosuppressive treatment.

What does the study involve?
All participants take calcium dobesilate capsules by mouth (two 500 mg capsules twice a day, totalling 2,000 mg per day) for 90 days alongside their usual medications. There is no placebo group. Patients attend five clinic visits: at the start of the study and then every 30 days through to day 120, which falls 30 days after the last dose of the study drug. At each visit, blood and urine samples are taken to measure kidney function, blood sugar control, cholesterol, and blood cell counts. The amount of protein in the urine is checked, leg veins are examined and graded using the CEAP classification, and patients fill in a quality-of-life questionnaire about how their vein symptoms affect their daily life. Any side effects are recorded, and leftover tablets are counted to check that the medication is being taken as prescribed.

What are the possible benefits and risks of participating?
Potential benefits include a reduction in urinary protein loss (suggesting less kidney damage), improvement in leg vein symptoms and quality of life, and close medical monitoring throughout the study period, with all study medication provided free of charge. The main known risk is a rare but serious drop in white blood cell counts (leukopenia), which can increase susceptibility to infections. Blood counts are monitored at every visit to detect this early. Other possible side effects include digestive discomfort, and the usual risks associated with routine blood draws.

Where is the study run from?
Instituto de Diabetes AC, Centro de Especialidades Médicas de Celaya, Guanajuato (México)

When is the study starting and how long is it expected to run for?
March 2024 to September 2025

Who is funding the study?
OM Pharma Group provided the study medication free of charge and funded the editorial and medical writing services

Who is the main contact?
Dr Juan Rosas Guzmán, drjrosas@gmail.com

Contact information

Type(s)
Scientific, Principal investigator, Public

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Study information

Scientific Title
Effect of calcium dobesilate on albuminuria, renal function and venous disease severity in patients with type 2 diabetes, albuminuric diabetic nephropathy and concomitant chronic venous insufficiency: a prospective single-arm interventional pilot study (CADOMIC)

Acronym
CADOMIC

Study objectives

To assess the change from baseline in log-transformed urinary albumin/creatinine ratio (A/C) over the 90-day treatment period, assessed at days 30, 60 and 90 (mixed-effects models).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/02/2024, Celaya Medical Specialties Center Ethics Committee (Calle Alvaro Obregon 209, Celaya, 38000, Mexico; +52 (0)4616121962; contacto@cemcelaya.com), ref: CEMC 2024-001

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Sequential

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Diabetic nephropathy and chronic venous insufficiency

Interventions
This prospective single-arm interventional pilot study evaluated whether calcium dobesilate (CaD), an endothelial-targeted agent, is associated with changes in albuminuria, renal function, venous disease severity and venous-related quality of life in 50 adults with T2D, albuminuric diabetic nephropathy and CEAP C3 or higher CVI. Participants received CaD 2,000 mg/day for 90 days added to standard care, followed by a 30-day post-treatment observation (washout) period.

Intervention Type
Drug

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Calcium dobesilate

Primary outcome(s)

1. Urinary albumin excretion measured using the urinary albumin-to-creatinine ratio (A/C, mg/g), determined from spot urine samples collected at baseline (day 0) and at days 30, 60, 90 (end of treatment), and 120 (end of 30-day washout). A/C values were log-transformed before analysis; longitudinal change was estimated using linear mixed-effects models with a random intercept per subject.

Key secondary outcome(s)
1. Renal function measured using estimated glomerular filtration rate (eGFR, ml/min/1.73 m²), calculated using the Modification of Diet in Renal Disease (MDRD) formula from serum creatinine values obtained at baseline and at days 30, 60, 90, and 120. Longitudinal change was assessed using linear mixed-effects models.

2. Clinical severity of chronic venous disease measured using the Clinical-Etiological-Anatomical-Pathophysiological (CEAP) classification, graded by clinical examination at baseline and at days 30, 60, 90, and 120. Change across ordinal categories was modelled using a cumulative link mixed model with logit link.

3. Venous disease-related quality of life measured using the Chronic Venous Insufficiency Questionnaire, 20-item version (CIVIQ-20) at baseline and at days 30, 60, 90, and 120

4. Glycaemic control measured using glycated haemoglobin (HbA1c, %) and fasting plasma glucose (mg/dL), obtained from venous blood samples at baseline and at days 30, 60, 90, and 120

5. Lipid profile measured using total cholesterol and triglycerides (mg/dl), obtained from fasting venous blood samples at baseline and at days 30, 60, 90, and 120

6. Safety and tolerability measured using complete blood count (including total leukocyte count) obtained at baseline and at each follow-up visit, together with continuous recording of adverse events and serious adverse events throughout the study period. Treatment adherence was assessed by tablet count at each monthly visit.

Completion date
09/09/2025

Eligibility

Key inclusion criteria
1. Confirmed type 2 diabetes (T2D) in clinically stable condition; diabetic nephropathy with albuminuria (urinary A/C ≥30 mg/g) and estimated glomerular filtration rate (eGFR) (Modification of Diet in Renal Disease [MDRD]) >30 and <90 ml/min/1.73 m²
2. Stable oral antidiabetic drugs or insulin ≥3 months
3. HbA1c 6.5–9%
4. Chronic venous disease of the lower limbs CEAP clinical class C3 or higher
5. In hypertensive patients, effective and/or maximally tolerated angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers (ACEI/ARB) and/or other antihypertensives

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
20 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Type 1 or secondary diabetes; pregnancy or lactation; hypersensitivity or intolerance to calcium dobesilate (CaD)
2. Nephrotic syndrome
3. eGFR <30 ml/min/1.73 m²
4. Uncontrolled hypertension (>160/100 mmHg)
5. Acute kidney injury
6. CEAP C0–C2
7. Treatment with SGLT2 inhibitors or GLP-1 receptor agonists
8. Known malignancy
9. Immunosuppressive therapy
10. Any condition precluding safe participation
11. Enrolment in another investigational drug study

Date of first enrolment
12/03/2024

Date of final enrolment
11/06/2025

Locations

Countries of recruitment
Mexico

Study participating centre
Centro de Especialidades Médicas de Celaya
Calle Alvaro Obregon 209
Celaya
Mexico
38000

Sponsor information

Organisation
OM Pharma SA

Funder(s)

Funder type

Funder Name
OM Pharma SA

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available