A randomized, double-blind, placebo-controlled, multi-center study to assess the efficacy and safety of BAY 2327949 in patients with chronic kidney disease (eGFR range from 25 to 60 mL/min/1.73 m²) due to type 2 diabetes or hypertension and at least one cardiovascular comorbidity

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To evaluate the efficacy of BAY 2327949 to decrease urine albumin-to-creatinine ratio (UACR) in patients with chronic kidney disease.To evaluate the safety and tolerability of BAY 2327949.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON49199

Source
ToetsingOnline

Brief title
ASSESS-CKD

Condition

- Cardiac disorders, signs and symptoms NEC
- Glucose metabolism disorders (incl diabetes mellitus)

- Nephropathies

Synonym
chronic kidney disease; damaged kidney

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer AG

Intervention

Keyword: cardiovascular comorbidity, chronic kidney disease, type 2 diabetes

Outcome measures

Primary outcome

Decrease in UACR at end of treatment (Visit 6) versus baseline (Visit 2).

Secondary outcome

Frequency of treatment- emergent adverse events (TEAEs).

Study description

Background summary

Chronic kidney disease can cause narrowing of the blood vessels in the kidneys, which impairs the microcirculation in the kidneys. Less oxygen is distributed, which is harmful to the kidneys. BAY 2327949 can decrease the narrowing of the blood vessels which may improve the microcirculation in the kidneys..

Study objective

To evaluate the efficacy of BAY 2327949 to decrease urine albumin-to-creatinine ratio (UACR) in patients with chronic kidney disease.
To evaluate the safety and tolerability of BAY 2327949.

Study design

This is a randomized, double-blind, parallel-group, placebo-controlled,

multi-center study.

Intervention

BAY2327949 60 mg (2 tablets of 30 mg, orally) once daily for 28 days.
Placebo: Matching placebo orally once daily for 28 days.

Study burden and risks

Patient's burden consists of the extra time investment during study participation.
The patient will be asked to come to the hospital 9 times in 2,5 months.
The patient could find the following activities as inconvenient:
- the quantity of the urine collection: up to 8x 3 containers
- the lab activities: up to 7 blood samples and 1x pharmacogenetic blood sample and
- up to 7x PK and/or biomarker samples (serum en plasma)

As BAY 2327949 is still in early development, there are no associated side effects to BAY 2327949. However there were adverse events reported in 2 completed trails with BAY 2327949. These adverse events are mentioned in the patient information form.

When the burden and risks are adversely experienced by the patient, the patient can stop the study participation, at any time, without providing an explicit reason and without any consequences for the further medical care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion Criteria:
- A clinical diagnosis of chronic kidney disease (CKD) with estimated glomerular filtration rate (eGFR) * 25 mL/min/1.73 m^2 but * 60 mL/min/1.73 m^2 (estimated using the CKD-EPI [Epidemiology Collaboration] equation) as assessed during Visit 1, and albuminuria (as measured by urine albumin-to- creatinine ratio [UACR]) in the range of * 30 but * 3000 mg/g, based on the first assessment for Visit 1.
- CKD with a clinical cause of either T2D or hypertension: -- if T2D is the clinical cause, history of type 2 diabetes mellitus as defined by the American Diabetes Association (on treatment with glucose- lowering medications and/or insulin) for at least 2 years before randomization and on a stable therapy with sodium-glucose transport protein 2 (SGLT2) inhibitor for at least 3 months before randomization; -- if hypertension is the clinical cause, patients must have a history of systolic blood pressure (BP) values * 140 mmHg and/or diastolic BP values * 90 mmHg, and on hypertension medication for at least 5 years before randomization.
- Stable treatment with either angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) at the maximal tolerated labelled daily dose and otherwise stable antihypertensive treatment both for at least 3 months before randomization. If taking an SGLT2 inhibitor, the participant must be on stable treatment for at least 3 months before randomization without any planned changes in dosing during the study period. All treatments must be expected to remain stable over the study period without any planned dose adjustments.
- Body mass index within the range of 18-38 kg/m^2 as evaluated for Visit 1.
- Male participants must agree to use barrier contraception (condoms). Female participants must be of non-child-bearing potential.

Exclusion criteria

- Known non-diabetic or non-hypertensive renal disease (e.g. autosomal dominant polycystic kidney disease or autosomal recessive polycystic kidney disease, bilateral clinically relevant renal artery stenosis, lupus nephritis, or ANCA-associated vasculitis, or any other secondary glomerulonephritis)
- Clinical diagnoses of heart failure and persistent symptoms (NYHA class III * IV), or hospitalization for worsening heart failure in the last 3 months prior to signing the ICF
- Uncontrolled hypertension indicated by > 160 mmHg systolic BP or *100 mmHg diastolic BP at Visit 1 or Visit 2 or at any unscheduled visit before randomization
- History of secondary hypertension (i.e., renal artery stenosis, primary aldosteronism, or pheochromocytoma) ; stroke, transient ischemic cerebral attack, acute coronary syndrome in the last 3 months prior to signing the ICF.
- Dialysis for acute renal failure within the previous 6 months prior to signing the ICF
- Renal allograft in place or a scheduled kidney transplant within the next 18 weeks from signing the ICF (being on a waiting list does not exclude the participant)
- Hepatic insufficiency classified as Child-Pugh B or C or other significant liver disease (e.g., acute hepatitis, chronic active hepatitis, cirrhosis as indicated by e.g. AST/ALT >3x ULN)
- Active malignancy. Previous malignancies are allowed if there is a 5-year remission- and treatment-free time before signing the ICF
- Any surgical or medical condition, which in the opinion of the investigator, may place the participant at higher risk from his/her participation in the study, or is likely to prevent the participant from complying with the requirements of the study or completing the study.
- For participants without diabetes: receiving off-label treatment with an SGLT2 inhibitor
- Indication for immunosuppressants, receiving cytotoxic therapy, immunosuppressive therapy, or other immunotherapy within 6 months prior to signing ICF
- Combination use of an ACE inhibitor and ARB within 3 months prior to signing ICF
- Concomitant therapy with drugs that strongly induce or inhibit CYP3A4 (cytochrome P-450 3A4), or that are inhibitors of P-gp (P-glucoprotein).
- Planned change of concomitant medications or dose adjustments during participation in this study
- Participation in another clinical study with treatment with another investigational product 90 days prior to signing ICF
- HbA1c > 11% at Visit 1.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO Date:	23-09-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-12-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-01-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	08-01-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2020-002192-35-NL
CCMO	NL74997.100.20