A randomized, double-blind, placebo-controlled, multi-center study to assess the safety and efficacy of different oral doses of BAY 94-8862 in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic nephropathy

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Primary objective of the study is•To investigate the change of Urinary Albumin-to-Creatinine ratio (UCAR) after 90 days treatment Secondary objectives of the study are•To assess safety and tolerability of these doses by assessing the effects on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON38909

Source
ToetsingOnline

Brief title
ARTS-DN

Condition

- Diabetic complications
- Nephropathies

Synonym
Diabetic Nephropathy, Kidney disease of diabetes

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Diabetic Nephropathy, Kidney disease of diabetes

Outcome measures

Primary outcome

Primary objective of the study is

•To investigate the change of Urinary Albumin-to-Creatinine ratio (UCAR) after

90 days treatment

Secondary outcome

Secondary objectives of the study are

•To assess safety and tolerability of these doses by assessing the effects on

serum potassium and renal function

•To assess change in health-related quality of life from baseline to 90 days of

treatment assessed by the Kidney Disease Quality of Life (KDQL) and EQ-5D-3L

questionnaires

Study description

Background summary

Current therapies for Diabetic Nephropathy (DN) rely on the control of proteinuria with Angiotensin Converting Enzyme Inhibitors (ACEIs) or Angiotensin II receptor blockers (ARBs). Studies have shown a direct relationship between an increase in plasma aldosterone after ACEI/ARBs

treatment and an increase in proteinuria and a decrease in kidney function. There is an urgent need to evaluate novel therapies to improve cardiovascular and renal outcomes in patients with diabetic nephropathy. The study medication, BAY94-8862 is expected to have the potential to address the unmet medical needs in patients with type 2 diabetes mellitus and the clinical diagnosis of DN. In a previous study with BAY94-8862, albuminuria was reduced, in particular in subjects with high and very high albuminuria at baseline. When added to standard therapy with ACEIs or ARBs treatment, BAY94-8862 might lead to a reduction in proteinuria compared with placebo on top of standard of care.

Study objective

Primary objective of the study is
•To investigate the change of Urinary Albumin-to-Creatinine ratio (UCAR) after 90 days treatment

Secondary objectives of the study are
•To assess safety and tolerability of these doses by assessing the effects on serum potassium and renal function
•To assess change in health-related quality of life from baseline to 90 days of treatment assessed by the Kidney Disease Quality of Life (KDQL) and EQ-5D-3L questionnaires

Study design

Multi-center, randomized, adaptive, double-blind, placebo-controlled parallel-group design

Intervention

Niet van toepassing.

Study burden and risks

Up to 8 study visits (Maximum study duration is 216 days)
Blood samples at each study visit.
Urine sample collection at 7 visits (3 samples collected over 3 days)
Two questionnaires to complete at 4 visits. EQ-5D-3L - 2 pages in length and KDQL consists of 36 questions.
Physical Examination at 5 visits.
ECG assessment at 7 visits.
Some patients may need to modify current medication before entering the study.
BAY94-8862 may have some therapeutic benefit, however this cannot be guaranteed. Patients are at risk of experiencing side effects.

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

Men and women aged 18 years and older. ;Subjects with type 2 diabetes mellitus ;Subjects with a clinical diagnosis of diabetic nephropathy (DN) based on at least 1 of the following criteria:;- Persistent very high albuminuria defined as urinary albumin-to-creatine ratio (UACR) of >/=300 mg/g in 2 out of 3 first morning void samples and estimated glomerular filtration rate (eGFR) >/=30 mL/min/1.73 m2 (CKD-EPI) or;- Persistent high albuminuria defined as UACR of >/=30 mg/g but <300 mg/g in 2 out of 3 first morning void samples and eGFR >/=30 mL/min/1.73 m2 (CKD-EPI);Subjects treated with an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB), but not both, for at least 3 months;Serum potassium

Exclusion criteria

Non-diabetic renal disease (confirmed by biopsy);Known bilateral clinically relevant renal artery stenosis (>75%) ;Hypertension with mean sitting systolic blood pressure (SBP) >/=180 mmHg or mean sitting diastolic blood pressure (DBP) >/=110 mmHg at the run-in visit or mean sitting SBP >/=160 mmHg or mean sitting DBP >/=100 mmHg at the screening visit;Subjects with a clinical diagnosis of heart failure with reduced ejection fraction (HFrEF) and persistent symptoms (New York Heart Association class II-IV) at the run-in visit;Stroke, transient ischemic cerebral attack, acute coronary syndrome, or hospitalization for worsening heart failure, in the last 30 days prior to the run-in visit

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-09-2013
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	BAY94-8862
Generic name:	BAY94-8862

Ethics review

Approved WMO Date:	02-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-08-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-11-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-01-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-02-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2012-004179-38-NL
ClinicalTrials.gov	NCT01874431
CCMO	NL44508.042.13