A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON50440

Source
ToetsingOnline

Brief title
SCORED

Condition

- Cardiac disorders, signs and symptoms NEC
- Diabetic complications
- Urinary tract signs and symptoms

Synonym
Diabetes mellitus type 2

Research involving
Human

Sponsors and support

Primary sponsor: Lexicon Pharmaceuticals, Inc.
Source(s) of monetary or material Support: Lexicon Pharmaceuticals;Inc.

Intervention

Keyword: Cardiovascular events, Diabetes type 2, Impaired renal function, Sotagliflozin

Outcome measures

Primary outcome

* The 2 primary objectives of this study are to demonstrate that, when compared

to placebo in patients with T2D, CV risk factors, and moderately impaired renal

function, sotagliflozin:

- Is non-inferior to placebo on the composite endpoint of CV death, non-fatal

MI, or non-fatal stroke (3-point MACE)

- Reduces the composite endpoint of CV death or HHF

Secondary outcome

* The secondary objectives of this study are to demonstrate that, when

compared to placebo in patients with T2D, CV risk factors, and moderately

impaired renal function, sotagliflozin:

- Reduces the composite endpoint of CV death, non-fatal MI or non-fatal stroke

(3-point MACE)

- In patients with Baseline eGFR *30 mL/min/1.73 m2, reduces the composite

renal endpoint of sustained *50% decrease in eGFR from Baseline (for *30 days),

chronic dialysis, renal transplant, or sustained eGFR <15 mL/min/1.73 m2 (for *30 days)

- In patients with Baseline eGFR *30 mL/min/1.73 m2 and Baseline UACR *300 mg/g (34 mg/mmol), reduces the composite renal endpoint of sustained *50% decrease in eGFR from Baseline (for *30 days), chronic dialysis, renal transplant, or sustained eGFR <15 mL/min/1.73 m2 (for *30 days)

- Reduces the composite endpoint of CV death, HHF, or urgent HF visit (defined in Appendix E)

- Reduces CV death

- Reduces all-cause mortality

* To assess the safety and tolerability of sotagliflozin in patients with T2D, CV risk factors, and moderately impaired renal function

Study description

Background summary

Type 2 diabetes (T2D) is a growing epidemic worldwide that is associated with a high incidence of macrovascular and microvascular complications. Type 2 diabetes is associated with cardiovascular (CV) risk factors such as dyslipidemia, hypertension, and obesity. Although microvascular complications have been shown to be decreased by glucose-lowering therapies, the effect on macrovascular outcomes is not as clear. The prevalence of T2D is increasing, and as the frequency of diabetes increases, so will its complications, including renal impairment, CV death, and heart failure (HF). Hence, the development of glucose-lowering therapies effective at decreasing the risk of CV death and HF and/or the progression of renal impairment is a growing unmet medical need.

Study objective

This study is designed to demonstrate the CV and renal effects of sotagliflozin in patients with T2D, high CV risk, and moderate renal impairment. One of the

major objectives of this study is to fulfill the regulatory mandate that any new therapy for T2D must demonstrate that its use does not result in an unacceptable increase in CV risk.

Study design

This study is a Phase 3, multicenter and multinational, randomized, double-blind,placebo-controlled, parallel-group study in approximately 10,500 patients with T2D, CV risk factors, and moderately impaired renal function. The study will consist of 3 periods:
* A Screening period of 1 to 4 weeks
* A randomized, Double-blind Treatment period including up-titration (the dose of sotagliflozin or matched placebo should be increased from 200 mg to 400 mg in the first 6 months of the randomized Double-blind Treatment period, if tolerated)
* A 14-day Post-treatment period

Intervention

Sotagliflozin 200 mg, 400 mg or placebo.

Study burden and risks

Risks and burdens related to blood collections, study procedures and possible adverse events of study medication.

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

-Type 2 Diabetes Mellitus with glycosylated hemoglobin (HbA1c) * 7%.,
-Estimated glomerular filtration rate (eGFR) * 25 and * 60 mL/min/1.73 m2.,
-Age 18 years or older with at least one major cardiovascular risk factor or age 55 years or older with at least two minor cardiovascular risk factors.,
-Signed written informed consent..

Exclusion criteria

-Antihyperglycemic treatment has not been stable within 12 weeks prior to screening., -Planned coronary procedure or surgery after randomization., -Lower extremity complications (such as skin ulcer, infection, osteomyelitis, and gangrene) identified during screening and requiring treatment at randomization., -Planning to start a sodium-glucose linked transporter-2 (SGLT2) inhibitor during the study.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2018
Enrollment:	115
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NVT
Generic name:	Sotagliflozin

Ethics review

Approved WMO Date:	25-10-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-02-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-05-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-06-2018
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-11-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-01-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-05-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-06-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-03-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-04-2020
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	EUCTR2017-002644-32-NL
ClinicalTrials.gov	NCT03315143
CCMO	NL63337.100.17