IMPROVE

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23733

Source
Nationaal Trial Register

Brief title
IMPROVE

Health condition

Type 2 diabetes
High Albuminuria

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

Reduction in 24-hr urinary albumin excretion

Secondary outcome

To assess:
-To assess the within-patient variability in HbA1c, 24-hr blood pressure, body weight, and

albuminuria response to dapagliflozin.
-To assess the between-patient variability in HbA1c, 24-hr blood pressure, body weight, and albuminuria response to dapagliflozin.
-The variability in HbA1c, blood pressure, body weight, and albuminuria in response to dapagliflozin during the first and second treatment period.

Study description

Background summary

Albuminuria is a risk marker of renal and cardiovascular disease progression. The variability in reponse with drugs that decrease albuminuria is large. This study is designed to assess the anti-albuminuric effects of dapagliflozin, a sodium-glucose transport inhibitor, and the variability in drug response

Study objective

- Dapagliflozin decreases albuminuria
- The response to dapagliflozin is variable in albuminuria
- The response in blood glucose, blood pressure, body weight and albuminuria varies within an individual

Study design

Albuminuria and variability will be assessed after 6 weeks therapy

Intervention

Dapagliflozin 10 mg/day or placebo

Contacts

Public
University Medical Center Groningen
S. Petrykiv
Groningen
The Netherlands
+31 50 363 2810
Scientific
University Medical Center Groningen
S. Petrykiv

Groningen
The Netherlands
+31 50 363 2810

Eligibility criteria

Inclusion criteria

-Age ≥18 and ≤75 years
-Diagnosis of type 2 diabetes mellitus
-HbA1c ≥ 6.6% and <11.0%
-Urinary albumin excretion > 100 mg/g
-On a stable dose of an ACEi or ARB for at least 4 weeks prior to randomization
-On a stable dose of blood glucose lowering medication for at least 4 weeks prior to randomization
-eGFR ≥ 45 mL/min/1.73m2
-Willing to sign informed consent

Exclusion criteria

Type 1 diabetes
Urinary albumin excretion > 3500 mg/day
Active malignancy
Pregnancy or breast feeding

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2014
Enrollment:	36
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4295
NTR-old	NTR4439
Other	METc Universitair Medisch Centrum Groningen : 2014/111

Study results

Summary results

n/a