# RAAS-blockade in type II diabetes: added effects of a low sodium diet and diuretics.

Published: 11-04-2008 Last updated: 15-05-2024

Determinination of the added effects of dietary sodium restriction or diuretic use to antihypertensive and antialbuminuric therapy.

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

## Summary

#### ID

NL-OMON35646

**Source** ToetsingOnline

Brief title DiNaMO

### Condition

- Diabetic complications
- Diabetic complications
- Nephropathies

**Synonym** diabetes, Type II diabetes

**Research involving** Human

### **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Groningen **Source(s) of monetary or material Support:** Ministerie van OC&W

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#### Intervention

Keyword: Albuminuria, Blood pressure, Dietary sodium restriction, Type II diabetes

#### **Outcome measures**

#### **Primary outcome**

Response of urinary albumin excretion to hydrochlorothiazide and a low sodium

diet during the different interventions.

#### Secondary outcome

Blood pressure response, renal function response en response of extracellular.

## **Study description**

#### **Background summary**

The worldwide incidence of diabetic nephropathy consequently to type II diabetes is increasing. Pathophysiology is complex and only partly explained. An increased extracellular volume associated with hypertension and albuminuria is tought to play an important role in the process. We hypothesize that modulation of extracellular volume by meanings of dietary sodium restriction or diuretic use in addition to a standardized blockade of the Renin Angiotensin System can potentiate antihypertensive and antialbuminuric therapy.

#### **Study objective**

Determinination of the added effects of dietary sodium restriction or diuretic use to antihypertensive and antialbuminuric therapy.

#### Study design

The research consists of a cross-over design in which both the sodium intake and diuretic is randomized. The cross-over is preceded by a pre-randomistaion phase with a duration of 4-12 weeks. During this phase patients will be adhered to the standard therapy of 40mg lisinopril 1dd1. This phase is followed by the cross-over phase consisting 4 periods of 6 weeks. Patients will be randomized for both the low (50 mmol) and high sodium (200 mmol) intake and 25 mg hydrochlorothiazide or placebo use. Total study extent is 28 to 36 weeks dependent on the dureation of the pre-randomisation phase.

#### Intervention

Study includes two interventions:

Patients will be randomized to low and high sodium intake in a cross-over design Patients will be randomized to 25 mg hydrochlorothiazide or placobo

#### Study burden and risks

Both hydrochlorothiazide and lisinopril both are broadly prescribed, type II diabetic patients included. Sodiumbromide has potential adverse events, but in the dose we use none have been reported. A sodium restricted diet may be burdensome but is has no particular risks. Patient burden consists of 6-8 visits to the outpatient clinic and a total of 10 24 hours urine collections. During each visit 10-20 ml of blood will be withdrawn and bloodpressure is measured in supine position for a period of 15 minutes.

## Contacts

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

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

### **Inclusion criteria**

Age between 18-70 years Type II diabetes Albuminuria > 30 mg/24h Stable 24h creatinine clearance >30 ml/min/1,73 m2

## **Exclusion criteria**

Contraindication for the use of lisinopril or hydrochlorothiazide Type I diabetes Myocardial infarction or stroke within 3 month prior to the research Kidneydisease unrelated to diabetes or hypertension Proteinuria >3 gr/24h Hypertension unresponsive to therapy during run-in period Inabilty for informed consent Incompliance to diet or studymedication Inaccordance with inclusioncriteria Pregnancy

## Study design

## Design

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

### Recruitment

NL Recruitment status:

Recruitment stopped

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Start date (anticipated):	01-05-2008
Enrollment:	55
Туре:	Anticipated

#### Medical products/devices used

Product type:	Medicine
Brand name:	hydrochlorothiazide
Generic name:	Hydrochlorothiazide
Registration:	Yes - NL intended use

## **Ethics review**

Approved WMO	
Date:	11-04-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	01-07-2010
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

ID: 24944 Source: Nationaal Trial Register Title:

#### In other registers

#### Register

EudraCT CCMO OMON ID EUCTR2008-001574-32-NL NL20366.042.08 NL-OMON24944