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

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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

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

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

Start date (anticipated):	01-05-2008
Enrollment:	55
Type:	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	ID
EudraCT	EUCTR2008-001574-32-NL
CCMO	NL20366.042.08
OMON	NL-OMON24944