RAAS-blockade in type II diabetes: added effects of dietary sodum restriction and diuretics.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24944

Source
Nationaal Trial Register

Brief title
DINAMO

Health condition

Diabetes Mellitus, proteinuria, albuminuria, hypertension, kidney disease, dietary sodium, RAAS-blockade

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. Albuminuria response;

2. Blood pressure response.

Secondary outcome

Extracellular fluid volume response.

Study description

Background summary

N/A

Study objective

To investigate the added effects of dietary sodium restriction and hydrochlorothiazide on top of ACEi, on albuminuria and blood pressure, in patients with diabetic nephropathy, and whether extracellular fluid volume is an intermediate factor in these.

Study design

Patients visit the outpatient clinic every 49th day of each study period for assessment of the endpoints (albuminuria, blood pressure) and safety parameters (potassium, renal function). At the 14th day of each period dietary sodium compliance (urinary sodium excretion) is checked.

Intervention

Combinations of:

1. Lisinopril 40 mg/d;

2. Hydrochlorothiazide 50 mg/d;

3. Normal diet;

4. Sodium restricted diet.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diabetic nephropathy;

2. Diabetes mellitus type II;

3. Proteinuria <3.0 g/24h;

4. Stable creatinine clearance > 30 mL/min;

5. Age 18 years or older.

Exclusion criteria

1. Diabetes mellitus type I;

2. Myocardial infarction or other cardiovascular or cerebrovascular event within the last 3 months prior to entry into the study;

3. Kidney disease other than caused by diabetes mellitus or hypertension;

4. Uncontrollable hypertension after the run- in period (>180/100 mmHg);

5. Serum potassium > 6.0 mmol/L;

6. Incompliance with regard to study medication or diet;

7. Unable to give informed consent;

8. Contraindication for the use of lisinopril or eplerenone.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2009
Enrollment:	55
Type:	Actual

Ethics review

Positive opinion

Date:	11-06-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35646
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2240
NTR-old	NTR2366
CCMO	NL20366.042.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35646

Study results

Summary results
Effects of sodium restriction and hydrochlorothiazide on RAAS blockade efficacy in diabetic nephropathy: a randomised clinical trial.
Kwakernaak AJ, Krikken JA, Binnenmars SH, Visser FW, Hemmelder MH, Woittiez AJ, Groen H, Laverman GD, Navis G; Holland Nephrology Study (HONEST) Group.
Lancet Diabetes Endocrinol. 2014 May;2(5):385-95. doi: 10.1016/S2213-8587(14)70030-0. Epub 2014 Mar 5.

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