Additief antiproteinurisch effect van de vitamine D analoog paricalcitol.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22539

Source
NTR

Brief title
VIRTUE-study

Health condition

proteinuria
proteinurie
albuminuria
albuminurie
chronic kidney disease
chronisch nierfalen
non-diabetic renal disease
niet-diabetische nierziekte
paricalcitol
zemplar
vitamin D receptor activator
vitamine D receptor activator
vitamin D
vitamine D

Sponsors and support

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

Medical Center Groningen.
Study medication provided by Abbott Inc.

Intervention

Outcome measures

Primary outcome

Albuminuria (24-hour urinary albumin excretion).

Secondary outcome

1. Mean arterial pressure (MAP);

2. Serum creatinine / creatinine clearance;

3. Plasma renin activity (PRA);

4. Renal hemodynamics (measured GFR, ERPF).

Study description

Background summary

The primary objective of the VIRTUE tudy is to determine the antialbuminuric response of vitamin D analogue in addition to ACE-inhibitor and low-sodium diet, in renal patients.

Study objective

Prevention of progressive renal function loss remains the main challenge in clinical nephrology. Blockade of the rennin-angiontensin-aldosterone system (RAAS), which can be potentiated by a low sodium diet, is the therapy of choice, but still many patients develop end-stage renal disease on the long term. Recent studies underline a crucial role for the vitamin D pathway in progressive renal function loss, possibly due to interference in the RAAS. We hypothesize that vitamin D (i.e. vitamin D receptor activator; paricalcitol) is able to blunt the reactive rise of renin levels seen in response to RAAS blockade, thus optimizing renoprotection.

Study design

Every 8 weeks.

Intervention

The study question will be addressed in a prospective, multiple-center, double-blind, crossover, randomized placebo-controlled clinical trial. Patients are consecutively treated during eight weeks with placebo or vitamin D analogue, respectively. At the same time, patients will be randomly assigned to either a liberal-sodium diet or a low-sodium diet. All patients receive a standardised dose of ramipril throughout the study.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male and female patients;

2. Non-diabetic renal disease as established by history, serum biochemistry tests and/or renal biopsy;

3. Age >18 years;

4. Residual proteinuria >300 mg/day and <10 g/day during conventional treatment of at

least 8 weeks with ACE-inhibitor or ARB at the maximum recommended dose;

5. Stable renal function (creatinine clearance > 30 ml/min/1.73m2; with < 6 ml/min per year decline);

6. Average of 2 consecutive PTH values of <8.7 pMol/L, 2 consecutive serum calcium levels between 2.0 and 2.6 mmol/l (corrected for albumin levels), 2 consecutive serum phosphorus levels of 1.5 mmol/l within 4 weeks prior to treatment;

7. Written informed consent.

Exclusion criteria

1. Uncontrolled hypertension, hyperkalemia (potassium >6.0 mmol/l, cardiovascular disease (myocardial infarction, unstable angina, percutanous transluminal coronary angioplasty, coronary artery bypass grafting, or stroke within last 6 months, heart failure NYHA III-IV), Diabetes Mellitus;

2. Epilepsy;

3. Liver disease resulting in aberrations of liver function tests;

4. Previously treated (within 3 months of screening) with paricalcitol or vitamin D (analogue);

5. Contraindication to ACEi, high/low-sodium diet or paricalcitol;

6. Medication interacting with ACEi or paricalcitol;

7. Frequent NSAID use (>2 doses/week);

8. Use of immunosuppressive drugs;

9. Use of digoxine;

10. Active malignancy;

11. Any bowel disorder resulting in fat malabsorption;

12. Pregnant or nursing (lactating) women, where pregnancy is defined as a state of a female after conception and until the termination of gestation, confirmed by a positive ß-hCG laboratory test (>5 mIU/ml);

13. Incompliance with diet or study medication;

14. Any psychiatric condition or psychofarmacon use;

15. Drug or alcohol abuse.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2012
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-05-2011
Application type:	First submission

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	NL2759
NTR-old	NTR2898
Other	METC UMCG / CCMO : 2009.272 / NL29900.042.09;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Publication policy is in agreement with the CCMO publication statement. Nor the sponsors, nor the principal investigator has a right of veto regarding the way of publishing the results.