Renal hemodynamic effects of aliskiren in comparison to ramipril.

No registrations found.

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

Summary

ID

NL-OMON28302

Source
Nationaal Trial Register

Brief title
renal HEALTH-STudY

Health condition

essential hypertension, glomerular hypertension, overweight, obesity

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. Renal hemodynamics (GFR, ERPF, FF);

2. Blood pressure.

Secondary outcome

1. Volume status (extracellular fluid volume - ECFV);

2. RAAS parameters (plasma renin activity, plasma renin concentration, angiotensin II, aldosteron);

3. Urinary and serum kidney injury markers.

Study description

Background summary

N/A

Study objective

Aliskiren can decrease glomerular pressure, in respect to ramipril, in patients with essential hypertension and overweight/obesity, independent from blood pressure.

Study design

After a wash-out period of 6 weeks, patients are randomly assigned to either a 6-week treatment period with aliskiren or a 6-week treatment period with ramipril in a cross-over design. Between both treatment periods an 8-week wash-out period is present. Renal hemodynamics are measured at start and end of both 6-week treatment periods.

Intervention

1. Aliskiren 1dd 300 mg p.o.;

2. Ramipril 1dd 10 mg p.o..

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Eligibility criteria

Inclusion criteria

1. Male caucasian patients;

2. Age >18 and <70 years;

3. Overweight or obese (BMI >27 and <35 kg/m2);

4. Essential hypertension according to WHO-criteria (systolic and diastolic bloodpressure >140 or <90 mmHg, respectively);

5. Normal renal function (creatinine clearance >90 ml/min/1.73m2);

6. Normo- or microalbuminuria (albuminuria <300mg/day);

7. Written informed consent.

Exclusion criteria

1. Inability to meet inclusion criteria;

2. Previously treated (within 3 months prior to start of study) with aliskiren or ramipril;

3. Cardiovascular disease (myocardial infarction, angina pectoris, percutanous transluminal coronary angioplasty, coronary artery bypass grafting, stroke, heart failure (NYHA I-IV), Diabetes Mellitus;

4. Active malignancy;

5. Any medication, surgical or medical condition which might significantly alter the absorption, distribution, metabolism, or excretion of medications including, but not limited to any of the following:

A. History of active inflammatory bowel disease within the last six months;

B. Major gastrointestinal tract surgery such as gastrectomy, gastroenterostomy, or bowel resection;

C. Gastro-intestinal ulcers and/or gastrointestinal or rectal bleeding within last six months;

D. Pancreatic injury or pancreatitis within the last six months;

E. Evidence of hepatic disease as determined by any one of the following: ALT or AST values exceeding 3x ULN at inclusion, a history of hepatic encephalopathy, a history of esophageal varices, or a history of portocaval shunt;

F. Evidence of urinary obstruction of difficulty in voiding at inclusion.

6. History of severe hypersensitivity or contraindications to ramipril or aliskiren;

7. Hypersensitivity to 125I-iothalamate or 131I-hippuran;

8. History of angioedema;

9. History of autonomic dysfunction (e.g. history of fainting or clinically significant orthostatic hypotension);

10. Participation in any clinical investigation within 3 months prior to start of the study;

11. Donation or loss of 400 ml or more of blood within 3 months prior to initial dosing;

12. History of drug or alcohol abuse within the 12 months prior to dosing, or evidence of such abuse as indicated by the laboratory assays conducted during the screening;

13. History of noncompliance to medical regimens or unwillingness to comply with the study protocol;

14. Any surgical or medical condition, which in the opinion of the investigator, may place the patient at higher risk from his/her participation in the study, or is likely to prevent the patient from complying with the requirements of the study or completing the study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2011
Enrollment:	16
Type:	Actual

Ethics review

Positive opinion

Date:	22-09-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34045
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2424
NTR-old	NTR2532
CCMO	NL33146.042.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34045

Study results

Summary results
N/A