ARIA: The effects of aliskiren on albuminuria in non-diabetic nephropathy patients treated with ramipril and volume intervention.

Gepubliceerd: 08-09-2011 Laatst bijgewerkt: 13-12-2022

1. Volume intervention by a diuretic and moderate sodium diet potentiates the antiproteinuric effects of aliskiren in patients with residual albuminuria during conventional RAAS-blockade; 2. Aliskiren neutralizes the reactive rise in plasma renin...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21705

Bron
Nationaal Trial Register

Verkorte titel
ARIA

Aandoening

Niet diabetische nefropathie/Non-diabetic nefropathy

Ondersteuning

Primaire sponsor: UMCG, Novartis
Overige ondersteuning: Novartis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Albuminuria.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

1. Volume intervention by a diuretic and moderate sodium diet potentiates the antiproteinuric effects of aliskiren in patients with residual albuminuria during conventional RAAS-blockade;

2. Aliskiren neutralizes the reactive rise in plasma renin activity that is associated with volume intervention during conventional RAAS-blockade in albuminuric patients.

Onderzoeksopzet

Each patient will undergo 4 treatment periods of 6 weeks according to the assigned treatment sequence. Patients will undergo baseline evaluation and after every treatment period of 6 weeks.

Onderzoeksproduct en/of interventie

The effect of aliskiren 300 mg in non-diabetic nefropathy patients treated with ramipril 10 mg and volume intervention (hydrochloorthiazide 25 mg and moderate sodiumdiet) will be investigated.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male and female outpatients at least 18 years old;

2. Non-diabetic renal disease as established by history, urine analysis, serum biochemistry tests and/or renal biopsy with residual albuminuria by UAER of >300 mg/24 hrs from 24 hour urine collection during conventional RAAS-blockade of at least 8 weeks of ACEinhibition or ARB treatment at the maximum recommended dose;

3. Glomerular Filtration Rate (GFR) >30 ml/min/1.73m2 as determined by creatinine clearance;

4. Patients with a history of hypertension and msSBP of <160 mm Hg and msDBP <105 mmHg at screening and baseline;

5. Patient must have a body mass index (BMI) within the range of 18 to 35 kg/m2.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previously treated (within 3 months of screening) with aliskiren or a combination of aliskiren and ramipril;

2. Renovascular hypertension or severe hypertension (msDBP ¡Ý110 mmHg and msSBP ≥ 180 mmHg);

3. Pregnant or nursing (lactating) women;

4. A medical history of unstable coronary artery disease, myocardial infarction, coronary bypass surgery or cerebrovascular accident within the last six months;

5. Diabetes mellitus (Type 1 and Type 2);

6. Heart failure NYHA class III-IV;

7. High rate of renal function loss (decline in creatinine clearance >6 ml/min/1.73m2 during the previous year or 1.5 ml/min/1.73m2 per month);

8. If subject is currently using and expected to continue or start any medication of concomitant medication;

9. Albuminuria >3 g/24h and/ or hypoalbuminaemia <28 g/L;

10. Serum potassium >5.3 mmol/L;

11. Recent (within the last three [3] years) and/or recurrent history of acute or chronic bronchospastic disease (including asthma and chronic obstructive pulmonary disease, treated or not treated);

12. Any medication, surgical or medical condition which might significantly alter the absorption, distribution, metabolism, or excretion of medications;

13. History of severe hypersensitivity or contraindications to any of the medications or drugs belonging to the similar therapeutic class (e.g. ARB, ACEi, renin-inhibitor, hydrochlorothiazide) as the study drugs and then excipients;

14. Hypersensitivity to 125I-iothalamate, 131I-hippuran and other test material used for the renal function test;

15. History of angioedema;

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

17. Participation in any clinical investigation within four (4) weeks prior to initial dosing or longer if required by local regulations, and for any other limitation of participation based on local regulations;

18. Donation or loss of 400 ml or more of blood within eight (8) weeks prior to initial dosing, or longer if required by local regulation;

19. History of immunodeficiency diseases, including a known positive HIV (ELISA and Western blot) test result in the past;

20. A known positive Hepatitis B surface antigen (HBsAg) or Hepatitis C test result in the

past;

21. 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 and/or at each baseline;

22. History of noncompliance to medical regimens or unwillingness to comply with the study protocol and dietary restrictions;

23. 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	32
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-09-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2916
NTR-old	NTR3063
Ander register	Novartis : SPP100A2260
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A