A 54-week, open-label, multicenter study to assess the long-term safety and tolerability of the combination of aliskiren 300 mg / valsartan 320 mg in patients with essential hypertension.

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The Primary objective is to assess the long-term (6 month and 12 month) safety of the combination of aliskiren 300 mg/ valsartan 320 mg in patients with essential hypertension (msDBP > 90 mmHg and < 110 mmHg.

Ethical review	Approved WMO
Status	Pending
Health condition type	Vascular hypertensive disorders
Study type	Interventional

Summary

ID

NL-OMON30026

Source
ToetsingOnline

Brief title
SPV2301

Condition

- Vascular hypertensive disorders

Synonym
high blood pressure, hypertony

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: aliskiren, hypertension, safety., valsartan

Outcome measures

Primary outcome

The assessment of safety will be based primarily on the frequency of adverse

events, laboratory abnormalities, and serious adverse events suspected by the

investigators to be related to study medications.

Secondary outcome

n.a.

Study description

Background summary

The Renin-angiotensin system (RAS) plays a major role in the regulation of arterial blood pressure and the pathogenesis of hypertension. Aliskiren is a new dug from a new class of antihypertensiva, the renin inhibitors. This renin inhibitor blocks the RAAS system at first level so angiotensin is no longer coverted into angiotensin I.
So far, aliskiren has been studied in more than 30 clinical studies both in healty people and in patients with hypertension or other heart and renal diseases. Valsartan belongs to a class of drugs called 'Angiotensin Rceptor Blockers (ARBs)'. It is an approved drug and available in may countries of the world. It has been studied extensively in clinical trials for treating patients with hypertension and has been shown to be generally well tolerated.
Hydrochloorthiazide (HCTZ) belongs to a class of drug called thiazide diuretics. It is an approved drug and available in may countries of the world. HCTZ works by affecting the kidney and increases elimination of certain minerals such as sodium and chloride and water which lowers blood pressure.

Study objective

The Primary objective is to assess the long-term (6 month and 12 month) safety of the combination of aliskiren 300 mg/ valsartan 320 mg in patients with essential hypertension (msDBP > 90 mmHg and < 110 mmHg.

Study design

This is an open label, phase III study. Each patient will have a screening visit. Treated patients will then enter the wash-out period of maximal 4 weeks. If the patient meets the in- and exclusioncriteria the patient will be treated with the combination aliskiren 150mg/ valsartan 160mg for 2 weeks. Subsequently the patient will be treated with the combination aliskiren 300mg/ valsartan 320 mg for 52 weeks. Starting from Visit 8, patients whose msSBP is * 140 mmHg and/ or msDBP * 90 mmHg for two consecutive visits may have hydrochlorothiazide (HCTZ) 12.5 mg added. If the patient*s msSBP remains * 140 mmHg and/ or msDBP remains * 90 mmHg after adding HCTZ 12.5, the dose of HCTZ can be increased to 25 mg.

Intervention

At Visit 4, all patients that meet study entry criteria will begin the initial treatment of aliskiren 150 mg / valsartan 160 mg for two weeks.
At Visit 5 (Day 14), the dose of the study medication will be force-titrated to aliskiren 300mg/valsartan 320mg.
Starting from Visit 8, patients whose msSBP is * 140 mmHg and/ or msDBP * 90 mmHg for two consecutive visits may have hydrochlorothiazide (HCTZ) 12.5 mg added. If the patient*s msSBP remains * 140 mmHg and/ or msDBP remains * 90 mmHg after adding HCTZ 12.5, the dose of HCTZ can be increased to 25 mg.

Study burden and risks

It cannot be guaranteed that the health of each patient will improve by participating in this study. Patients will be checked up regularly during this study and medication will be dispensed at no costs. The results of this study might help other patients with hypertension.
Possible discomforts of the study are: visiting the centre 13 times for bloodpressure and pulse measurements. One EKG will be made and blood will be drawn during 11 visits containing about 6-7 teaspoons. Blooddraws can cause some discomforts or some bruising. In rare cases an inflammation may occur.

Contacts

Public
Novartis

Raapopseweg 1
6824 DP
Nederland
Scientific
Novartis

Raapopseweg 1
6824 DP
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Outpatients 18 years of age and older.
2. Male or female patients are eligible.
3. For newly diagnosed/untreated patients with essential hypertension defined as DBP > 90 and < 110 mmHg at Visit 1 and Visit 2.
4. For previously treated patients with essential hypertension defined as DBP > 90 and < 110 mmHg after 2 to 4 weeks of washout (Visits 3 or 4).

Exclusion criteria

1. Severe hypertension (msDBP >110 mmHg and/or msSBP > 180 mmHg)
2. History or evidence of a secondary form of hypertension
3. Any history of hypertensive encephalopathy or cerebrovascular accident, or history within 12 months from visit 1 for transient ischemic attack (TIA), myocardial infarction, coronary bypass surgery, or any percutaneous coronary intervention (PCI).
4. Previous or current diagnosis of heart failure (NYHA Class III-IV).
5. Patients with Type 1 or Type 2 diabetes mellitus who are not well controlled based on the investigator's clinical judgment. Patients with diabetes mellitus enrolled in this study should

be well controlled. It is recommended that patients currently being treated for diabetes mellitus be on a stable dose of antidiabetic medication for at least 4 weeks prior Visit 1.
6. Current angina pectoris requiring pharmacological therapy except for nitrates.
7. Atrial fibrillation or atrial flutter at Visit 1, or potentially life-threatening arrhythmia during the 12 months prior to Visit 1

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-10-2006
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Diovan
Generic name:	valsartan
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	generiek verkrijgbaar
Generic name:	hydrochloortiazide
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	nog niet geregistreerd
Generic name:	aliskiren

Ethics review

Approved WMO Date:	25-08-2006
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	09-11-2007
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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
EudraCT	EUCTR2006-002621-23-NL
CCMO	NL13877.072.06