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Sponsor/company:	sanofi-aventis	ClinicalTrials.gov Identifier:	NCT00507845
		Study Code:	RAMIP_L_01961
Generic drug name:	Ramipril-felodipine	Date:	16/Apr/2009

Title of the study:	*Use of Ramipril and Felodipine Combination Therapy in Hypertension: An Effectiveness Study with Local Patients in Argentina.* RAMIP_L_01961		
Investigator(s):	Dr. Orias Marcelo, Córdoba, Argentina		
Study center(s):	21 sites, Argentina		
Publications (reference):	NA		
Study period: Date first patient/subject enrolled: 29-Jun-2007 Date last patient/subject completed: 21-Apr-2008		Phase of development: IV	
Objectives:	Primary: To assess the effectiveness of ramipril-felodipine (Triacor®) in hypertensive Argentinean patients Secondary: To assess the tolerability of ramipril-felodipine (Triacor®) in hypertensive Argentinean patients.		
Methodology:	Local, open-label, longitudinal, non-randomized multicenter study. 3 visits : Visit 1 baseline visit Visit 2 (week 4) In uncontrolled patients increase of the dosage of ramipril-felodipine from 2.5/2.5 mg to 5/5 mg Visit 3 (week 8): final visit		
Number of patients/subjects:	Planned: 369	Randomized: not randomized study. 266 patients included	Treated: 251 (15 patients didn't met the inclusion/exclusion criteria)
Evaluated:	Efficacy: 231 (patient who completed Visit 3)	Safety: 251	Pharmacokinetics: not applicable
Diagnosis and criteria for inclusion:	Outpatient hypertensive adults, with uncontrolled hypertension (Systolic blood pressure (SBP) ≥ 140 for all the patients and SBP ≥ 130 for diabetic patients and diastolic blood pressure (DBP) ≥ 90 for all the patients and DBP ≥ 80 for diabetic) after at least 6 weeks of monotherapy (calcium channel blockers, diuretics, beta-blockers, ACE-inhibitors; AT2 blockers)		

Investigational product: Dose: Administration:	Ramipril-felodipine Ramipril/felodipine 2,5/2,5 mg/day – Ramipril/felodipine 5/5 mg/day in uncontrolled patients at week 4 Per Os (PO)
Duration of treatment: 8 weeks.	Duration of observation: 8 weeks
Reference therapy:	Not applicable
Criteria for evaluation:	
Efficacy	Primary endpoints Primary effectiveness variables are the mean changes in systolic blood pressure (SBP) in comparison to baseline after 8 weeks of combined treatment. Secondary endpoints Mean changes in diastolic blood pressure (DBP) from baseline to Week 8 Percentage of responders with regard to diastolic and systolic blood pressure. Responders are defined as patients with diastolic pressure at week 8 of less than 90 mmHg (<80 mmHg for diabetics). For systolic blood pressure, responders are defined as patients with a systolic pressure at week 8 of less than 140 mmHg (<130mmHg for diabetics).
Safety:	Occurrence of adverse events after treatment and at each follow-up visit. Tolerability and safety will be assessed on the basis of reported adverse experiences and clinical examinations.
Statistical methods:	Statistical analysis was based on all evaluable patients. Data were summarized using mean, median, standard deviation and range for continuous parameters, and counts and percentages for categorical parameters. All statistical tests were conducted using tests in a bilateral significance level of 5%. Descriptive analysis was performed detailing patient characteristics (demographic data, treatment).
Summary:	Patients baseline characteristics Age 62.3 ±11.9; females 63%; diabetics 12% (97% Type 2); smokers 11%; overweight 23%; obesity 32%; sedentary 60%; hypercholesterolemia 44%; familiar history of cardiovascular disease 21%; stroke 4%; coronary artery disease 4%; heart failure 0.4%; peripheral artery disease 4%. Previous treatments: angiotensin converting enzyme inhibitors (ACEi) 54.8%; beta blockers 12%; angiotensin receptor blockers (ARB) 16.4%; calcium channel blockers 12%; diuretics 4.4%; alpha blockers 0.4%. Mean Basal BP 156.7mmHg/93.8mmHg ± 8.98mmHg/6.06mmHg Antihypertensive efficacy: 90.84% of patients completed the study treatment Mean changes of Systolic BP (SBP) between Visit 1 and Visit 3 27.9 mmHg±12.8mmHg (p<0.0001) and mean changes of Diastolic BP (DPB) between Visit 1 and Visit 3 16.3mmHg±9.3mmHg (P<0.0001). Mean BP at Visit 3: 128.8mmHg/77.7mmHg ± 10.49mmHg/8mmHg. SBP target was reached by 80.1% of the patients (p<0.00001) and DBP target by 86.6% (p<0.00001). The proportion of patients with both controlled SBP and DBP was 86.09% when considered by the physicians and 79.65% according to the targets defined by protocol. At V2 61.73% of the patients were uptitrated to ramipril/felodipine 5/5 and 38.27% of the patients continued during the whole study with 2.5/2.5 mg.
Safety results:	The drug was well tolerated. 8.37% of patients (n=21) experienced adverse events (Visit 2 3.98%, Visit 3 4.78%) 3.8% discontinued from treatment). The most frequent adverse events were cough (2.39%), aedema (1.19%) and cutaneous flush (1.19%). Only one patient experienced a serious adverse event (syncope) 0.4%. Tolerability evaluated by the physician in Visit 3 was considered as excellent 81.8%; good 15.6%; moderate 1.3%; poor 1.3%..
Date of report:	06-April-2009