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Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NA
		Study Code:	L_8261
Generic drug name:	Irbesartan	**Date:**	05/July/2007

Name of Sponsor/Company: sanofi-aventis de Colombia S.A.	Individual Study Table Referring to Part of the Dossier	*(For National Authority Use only)*
Name of Finished Product: Aprovel®		
Name of Active Ingredient: Irbesartan		

Title of Study: Comparative study of Irbesartan vs. Atenolol effects over endothelial function in hypertensive subjects with metabolic syndrome

Investigators: Patricio López-Jaramillo, MD, PhD; Jose Luis Accini. MD
Co-investigators: Carlos Luengas, MD; Rodrigo Botero, MD; Federico Silva, MD

Study centre(s): Instituto de investigaciones / Fundación Cardiovascular de Colombia.
Calle 155 A No 23-58, Tercer Piso, Instituto del Corazón.
Floridablanca, Santander, Colombia

Publication (reference): NA

Studied period (years): (date of first enrolment: August 2002) (date of last completed: July 2004)	**Phase of development:** IV

Objectives: Determine if the short term (12 weeks) treatment with Irbesartan had a beneficial effect over insulin resistance, endothelial function and the plasma levels of inflammatory markers, in hypertensive, non diabetic subjects with metabolic syndrome.

Methodology: Double bind, randomized controlled trial to compare the acute effects of Irbesartan (150 mg/day) vs. Atenolol (50 mg/day) over insulin resistance index (HOMA), flow mediated vasodilatation (FMV), carotid intima-media thickness (IMT) and the plasma of ultrasensitive GReactive Protein, in 86 hypertensive non diabetic subjects with Metabolic Syndrome.

Number of patients (planned and analyzed): Planned: 108, analyzed per protocol: 86.

Diagnosis and main criteria for inclusion:

- Men's between 18 and 80 years old
- Arterial hypertension stage 1 or 2 (Systolic arterial pressure > 130 mm Hg and/or diastolic blood pressure > 85 mm Hg)

At least two of the following criteria:

- Body Mass Index (BMI) >25 Kg/m2
- Fasting triglyceride plasma concentration > 150 mg/dL
- Fasting high density cholesterol (HDL) plasma concentration < 40 mg/dL
- Fasting plasma glucose concentration > 100 mg/dL and < 126 mg/dL

Test product, dose and mode of administration: Irbesartan 150 mg/day (Aprovel®), oral way.

Duration of treatment: 12 weeks.

Reference therapy, dose and mode of administration: Atenolol 50 mg/day, oral way.

Criteria for evaluation:
Efficacy: Insulin resistance index (HOMA), flow mediated vasodilatation (FMV), carotid intima-media thickens (IMT), plasma levels of ultrasensitive C-Reactive Protein.

Safety: Frequency of adverse drug reactions.

Statistical methods:
Patient information was reviewed two times to avoid errors. The principal method to compare was based in the observation into each subject between wash out and 12 weeks follow up. To determine statistical significance between statistical differences into the groups were used a t-test or a Wilcoxon's Rank Sum test in the continuous variables and a chi2 or Spearman test to categorical variables according with data distribution. To analyze blood pressure variables was used ANOVA test. A $p < 0.05$ value was considered as statistically significative.

SUMMARY:

EFFICACY RESULTS:
No differences on cardiovascular risk factors prevalence, anthropometrical parameters, pharmacological or personal antecedents were detected between treatment groups. Both treatments cause a progressive and comparable decrease in arterial blood pressure and improve the endothelial dependent and independent vasodilatation. No changes were observed in carotid intima-media thickens or any other biochemical parameter independently of the treatment received. Both treatments were well tolerated and no serious adverse events were presented.

SAFETY RESULTS:
During the trial 3 subjects were withdrawal by adverse events (1=nausea; 2=diarrhea). Neither required hospitalary treatment. One of the diarrheas was in an Atenolol treatment patient and others two in subjects in Irbesartan treatment.

Date of the report: Based on the data results inform of march 15, 2007