| *These results are supplied for informational purposes only.*<br>*Prescribing decisions should be made based on the approved package insert in the country of prescription* | | | |
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| **Sponsor/company:** | **sanofi-aventis** | **ClinialTrials.gov Identifier:** | **NA** |
| | | **Study Code:** | **L_9130** |
| **Generic drug name:** | **Irbesartan** | **Date:** | **November 20th, 2006** |

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| Title of Study: | The comparison of irbesartan with atenolol for the effects on endothelial dysfunction in type II diabetes patients with hypertension |
| Investigator: | Prof. Dr. Nevres Koylan |
| Study center: | Istanbul University Istanbul Faculty of Medicine Department of Cardiology, Turkey |
| Publication reference: | None |
| Study period: | 4 months |
| Phase of development: | Phase IV |
| Objectives: | Primary: Evaluation of the effect of irbesartan on nitric oxide (NO), which has key role in the endothelial dysfunction and the development of pressure vasomotor response, compared to standard therapy (atenolol)<br>Secondary: Evaluation of the effect of irbesartan on chronic inflammatory process and tendency for procoagulation, associated with endothelial dysfunction, compared to atenolol. |
| Methodology: | Prospective, standard therapy controlled, randomized, open, single center study |
| Number of patients: | Included: 44<br>Analysed: 44 |
| Diagnosis and main criteria for inclusion: | Patients, who were 40-65 years of age, type II manifest diabetes according to ADA criteria and mild to moderate hypertensive (180-140 mmHg systolic and 110-90 mmHg diastolic blood pressure), were included to the study. Secondary hypertension, congestive heart failure, azotemia, type I diabetes, liver failure, pregnancy and lactation and cancer were exclusion criteria. |

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| Test product, dose,<br>mode of administration<br>and batch number | Tablets containing 150 or 300 mg of irbesartan:<br>Karvea 150 mg/day, oral tablet<br>Karvea 300 mg/day, oral tablet<br>Karvezide 150 mg/day, oral tablet<br>Karvezide 300 mg/day, oral tablet |
| Reference therapy,<br>dose and mode of<br>administration | Tablets containing 50 or 100 mg of atenolol<br>Nortan 50 mg/day, oral tablet<br>Nortan 100 mg/day, oral tablet |
| Duration of treatment | 3 months |
| Criteria for evaluations: | Efficacy: Primary criterion of efficacy was high resolution Doppler ultrasonography for the evaluation of vasomotor function. Secondary criteria of efficacy were sICAM-1, sVCAM, sE-selectin, endotelin-1, IL-10, IL-6, CRP and PAI-1 for the evaluation of chronic inflammation and tendency for procoagulation.<br>Safety: Frequency, severity, causal relation to study drugs, duration and result of adverse events during the study. |
| Statistical methods: | Data for sociodemography, medical history, physical examination and evaluation criteria were summarized using descriptive statistics (like percentage, ratios, arithmetic means and standard deviations). In-group and between-groups comparisons were performed using parametric or nonparametric tests depending on the characteristic of data.<br><br>Significance limit was defined as $p<0.05$. |
| Conclusions: | Compared to the standard antihypertensive therapy (atenolol), irbesartan;<br>• has same antihypertensive effect,<br>• has same decreasing effect on urine albumin and creatinine,<br>• has same effect on inflammation process and tendency for procoagulation,<br>• has more beneficiary effect on vasomotor response,<br>• is safe like standard therapy,<br>on hypertensive type II diabetic patients. |
| Date of report: | February 1st, 2006 |