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Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NCT00268645
		Study Code:	HOE901_5036
Generic drug name:	Insulin Glargine	**Date:**	26/Sept/2007

Title of the study:	An Open Trial to Confirm The Efficacy, Tolerability And Safety Profile of Lantus® in Everyday Medical Practice in Type 2 Diabetes Patients Already on Insulin Therapy or in Type 2 Diabetes Insulin Naive Patients With Inadequate Glycaemic Control on One or Combination of Oral Antidiabetic Agents (ROLLING WAVES)		
Investigator(s):	Prof. Dr. Şazi İMAMOĞLU (Study coordinator) Uludag University Medical Faculty Endocrinology Department Bursa, Turkey		
Study center(s):	54 centers from Turkey		
Study period: Date first patient enrolled: 02-Oct-2004 Date last patient completed: 17-May-2006		**Phase of development:** IV	
Objectives:	To confirm the efficacy, and safety profile of Lantus in everyday medical practice.		
Methodology:	Open, non-controlled		
Number of patients:	Planned: 540	Randomized: NA	Treated: 519
Evaluated:	Safety: was evaluated using the adverse events reported during the project and the level of insulin antibody		
Diagnosis and criteria for inclusion:	- Patients with type 2 diabetes mellitus - Age > 18 years - Already treated with insulin or insulin naive patients with inadequate glycemic control on one or combination of oral antidiabetic agents, - HbA1c > 8		
Investigational product: Dose: Administration:	Insuline glargine Individually adjusted Subcutaneous injections		
Duration of treatment: 3 months		**Duration of observation:** NA	

Reference therapy: Dose: Administration:	NA NA NA
Criteria for evaluation:	The following safety criteria were evaluated, and analyzed using descriptive statistics. For sub-group comparisons, appropriate parametric or non-parametric test was performed according to type of data. Statistical significance level was defined as $P < 0.05$.
Efficacy:	The primary efficacy assessment was the evolution of fasting blood glucose level and HbA1c (when available). The efficacy was also evaluated using the investigator's satisfaction assessment.
Safety:	The safety was evaluated using the adverse events reported during the project and the level of insulin antibody.
Statistical methods:	The average fasting blood glucose, HbA1c values and Lantus doses were summarized by mean, minimum and maximum, and the physicians' assessment of efficacy and tolerability of the treatment were summarized by frequency and percentage. For continuous variables Wilcoxon test was used to compare visits in case of a non normal distribution. Categorical variables were analyzed by using crosstab statistics. The level required for statistical significance of the primary comparison was set at 0.05.

Summary:	Totally 519 patients, 202 already treated with insulin and 317 insulin naïve, were included in the study. The mean age of insulin naïve patients was 53.9±9.3 years and it was 52.6±11.5 for patients already treated with insulin. Of the patients in study groups 46.0% were male and 34.7% were female. The initial dose of Lantus was 11.8±4.5 IU for insulin naïve patients and 19.8±9.5 IU for patients already treated with insulin. The dose titration was performed according to algorithm provided in the study in 80.4% and 82.2% of insulin naïve and already insulin treated patients, respectively.
Efficacy results:	The percentage of HbA1c decreased significantly for both groups (*P*<0.001). For over 95% of patients, investigators and patients were very satisfied or satisfied with treatment. According to patients' diary, Lantus treatment decreased the fasting and post-prandial blood glucose levels for every measurement time for both insulin naive patients and patients already treated with insulin (*P*<0.001). Fasting blood glucose level significantly decreased from initial 245.5±73.0 mg/dL to 127.1±40.3 mg/dL for insulin naïve patients (P<0.001), and it significantly decreased from 236.5±86.0 mg/dL to 139.7±57.3 mg/dL for patients already treated with insulin (*P*<0.001). Hypoglycemia was developed in 18.9% of insulin naive patients and 31.3% of patients already treated with insulin.
Safety results:	Among insulin naïve patients, 13 adverse events were reported during the study. The adverse event number was 8 for patients already treated with insulin.. The most common adverse event reported was hypoglycemia. Of these adverse events, 1 in each group was reported as serious Two serious adverse events: one in the group under insulin treatment (64 years old male has experienced myocardial infarction, which was unrelated to the study insulin, so no procedure in regard to antidiabetic treatment is performed), and the other in the group which was not under insulin treatment (67 years old male with fungal infection. This event was not also related to the study treatment). The percentage of insulin antibody decreased significantly with study treatment for patients already treated with insulin, but it did not change for insulin naive patients. In insulin naïve patients insulin antibody level was 7.5±7.8 in initial and it was 7.2±8.1 just after the study was completed. In patients who have already treated with insulin, it was 14.6±13.8 in initial and it was 12.4±11.5 just after the study was completed.
Date of report:	14-Sep-2007