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Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NCT00576368
		Study Code:	HOE901_5007
Generic drug name:	insulin glargine	**Date:**	28 December 2007

Title

An open therapeutic project to confirm the efficacy, tolerability and safety profile of Lantus ® in everyday medical practice.

Investigator(s), study site(s)

120 Investigators

Study duration and dates	6 June 2003 – 30 April 2004	**Phase**	IV

Objectives

The objective of this survey on this registered product was to confirm the efficacy, tolerability and safety profile of Lantus ® in everyday medical practice.
This program will also help to obtain information about the use of the insulin titration regimen and handling of the Lantus ® insulin analogue.

Study design

Open, non-controlled, multicenter

Number of subjects planned

4000 patients (130-150 centres)

Inclusion criteria

All newly diagnosed diabetics and existing diabetics uncontrolled on other anti-diabetic therapy, where treatment with basal insulin is required to control hyperglycaemia, and who the treating investigator considers may benefit from the treatment with Lantus ® , could enter in this program.

Treatments

Lantus® was provided by Aventis for the purpose of this survey.

Dosage schedule: The physician had to be guided by the prescribing information outlined in the summary of products characteristics. The administration was done by once daily subcutaneous injection.

Duration of treatment per patient: at least 3months, until Lantus® was launched in Belgium/ GD Luxemburg

Safety data

The term "adverse event" covers any sign, symptom, syndrome, or illness that appears or worsens in a patient during the RECORD and that may impair the well being of the patient. The term also covers laboratory findings or results of other diagnostic procedures that are considered to be clinically relevant (e.g. that require unscheduled diagnostic procedures or treatment measures, or result in treatment discontinuation).

Statistical procedures

The average Fasting Blood Glucose (FBG), HbA1c values and Lantus® will be charted and the Patient satisfaction and physician‘s assessment of efficacy and safety of the treatment will be recorded as percentages.
A descriptive analysis of all adverse events reported will be performed.

Ethical and Legal aspects

Local, legal and regulatory requirements must be fulfilled in the collection of data. This project has been reviewed by an Ethics Committee.

Interim analysis

No interim analysis was performed.

Results - Study subjects and conduct

Data from a total of 3836 patients were collected

120 physicians participated in this program

Mean age of patients was 44.2 years (+- 16.24)

3230 patients (84.2%) were type 1 diabetes

586 patients (15.3%) were type 2 diabetes

In 20 cases (0.5%) this data was missing

Median duration of diabetes was 168 months, or 14 years

Before initiation of Lantus, patients were treated with different antidiabetic therapies. Overall, 10 sub-groups could be defined.

The vast majority of patients had an intensified insulin therapy before the start of Lantus (n = 3568; 93%):

- 1724 patients (44.9%) were treated with a basal-bolus insulin scheme with regular short-acting human insulin.

- 1815 patients (47.3%) were treated with a basal-bolus insulin scheme with a short-acting insulin analogue.

- 29 patients (0.8%) received insulin pump therapy

39 patients (1%) previously received 1 single injection of insulin in combination with OAD

125 patients (3.3%) received 2 injections of insulin, with (n = 37; 1%) or without (n = 88; 2.3%) OAD

61 patients (1.6%) received OAD only

38 patients (1%) received no antidiabetic treatment before start.

Glycemic status was suboptimal:

- mean FBG was 216.8 mg/dl

- mean FPG was 201 mg/dl

- mean HbA1c was 7.9%

Many patients suffered from hypoglycemia during the last 3 months before start:

- 2804 patients (73.1%) reported at least 1 hypoglycemic episode during the last 3 months before start
- 614 patients (16%) reported having had severe hypoglycemia, with a mean number of 3.8 episodes (+-6.95)
- 1667 patients (43.5%) reported nocturnal hypoglycemia, with a mean number of 7 episodes (+-5.49)

Lantus Initiation:

Insulin glargine was started at a mean dose of 21.8 IU; at the end, the mean dose reached was 22.8 IU (+-11.7). Difference vs. start dose was + 1IU.

Concomitant antidiabetic treatment was mainly short-acting insulin::

- 3681 patients (96%) received an intensified insulin therapy, with short-acting insulin in combination with insulin glargine

Mean duration of insulin glargine treatment was 146.3 days (+-63.98), or almost 5 months.

Results – Efficacy

Compared to baseline values, fasting glycemia decreased with 32.7 mg/dl (FBG) or with 20 mg/dl (FPG). These changes lead to an overall improvement of glycemic control as observed in the decrease of HbA1c from 7.9% to 7.66% (- 0.24%)

Results - Safety

During the trial a total of 87 adverse events (2.3%) were reported, 41 of those were Serious Adverse Events.

The 3 SAE's judged related to the treatment were known potential AE's of insulin therapy: hypoglycemia (2 cases) and – rarely - allergic reaction (1case).

15 SAE's resulted in death,without causal relationship with Lantus®; the cause of death in each case could clearly be linked to the medical history of the patient.

In total, 24 episodes of hypoglycemia (0.62%) were reported, 7 of these were nocturnal (0.18%) and 6 severe episodes (0.16%).

Results – Patient satisfaction

Overall satisfaction was very high (89.2%) in patients, with perceived reductions in nocturnal and severe hypoglycemia compared to the period before initiation of insulin glargine.

Results – Physician satisfaction

More than 90% of physicians rated the new treatment with insuline glargine as effective and well tolerated and expressed their intention to continue the treatment.

Report Date

30 May 2005