ORIGIN Trial
Hamilton Health Sciences
David Braley Cardiac, Vascular and Stroke Research Institute
Hamilton General Hospital Campus
237 Barton Street East
Hamilton, Ontario L8L 2X2
Phone : 905-527-4322 ext. 40566
Fax 905-297-3783
Email : origin@phri.ca

ORIGIN Press Release Regarding Glargine Insulin and Cancer

A recently published database analysis has raised the suspicion of a link between the use of glargine insulin and cancer. Although the results of this report were not confirmed in other database analyses, it has generated questions about the safety of glargine insulin. Such questions can best be answered by prospective, long-term follow-up of large numbers of patients enrolled in randomized trials of glargine versus other therapies.

The ORIGIN trial (Outcome Reduction with an Initial Glargine INtervention) randomized more than 12,500 people with dysglycemia (elevated glucose levels due to impaired fasting glucose, impaired glucose tolerance or early diabetes) to 1 injection of insulin glargine per day versus usual care. It is determining whether targeting normal fasting glucose levels with insulin glargine reduces cardiovascular outcomes compared to standard management. Participants have been followed for an average of 4 years to date for a total exposure of over 50,000 person years. Data are collected related to all major serious health outcomes, including cancers. Accumulating data are reviewed regularly by an Independent Data Monitoring Committee charged with auditing the safety of the trial. In light of the questions raised by the recent publications, this committee of experts has recently reviewed data related to cancers in both treatment groups and has concluded that there is no cause for concern and no reason to alter the design of the study for safety reasons.

The study is due to end in 2011, at which point detailed analyses will be published. In the meantime, the data will continue to be collected and audited for safety by this independent group. The researchers and the manufacturer of insulin glargine do not (and will continue to not) have access to data summarizing outcomes by treatment group.

ORIGIN Study: August 5, 2009

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