Biosimilar insulin lispro shown not inferior to Humalog in efficacy or safety

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Credit: Mary Ann Liebert, Inc., publishers

A study comparing the safety and efficacy of SAR342434, a biosimilar (follow-on form) of insulin lispro-Humalog, found it to be comparable to that of the brand name drug in patients also using insulin glargine. The phase 3, randomized SORELLA 1 trial evaluated changes in HbA1c, fasting plasma glucose, and self-monitored plasma glucose levels, as well as hypoglycemic events, and the results are published in *Diabetes Technology & Therapeutics*.

Coauthors Satish Garg, University of Colorado Denver (Aurora), Karin Wernicke-Panten and Yvonne Kirchhein, Sanofi-Aventis Duetschland (Frankfurt, Germany), Maria Rojeski, Sanofi (Bridgewater, NJ), Suzanne Pierre, Sanofi (Paris, France), and Krystyna Jedynasty, Centrum Diabetologiczne (Warsaw, Poland) collaborated on the article entitled "Efficacy and Safety of Biosimilar (SAR342434 Insulin Lispro) in Adults with Type 1 Diabetes also Using Insulin Glargine—SORELLA 1 Study."

Throughout the 6-month main study and additional 6-month safety extension period, the incidence and prevalence of hypoglycemia, treatment-emergent adverse events, and anti-insulin antibodies did not differ significantly between the two treatment groups.

"This is the first long-term study of biosimilar (follow-on) rapid-acting insulin (insulin lispro), evaluated for 1 year, which clearly shows the safety and efficacy of the biosimilar insulin being similar to the original insulin," says DTT Editor-in-Chief Satish Garg, MD, Professor of Medicine and Pediatrics at the University of Colorado Denver (Aurora). "The costs of insulin products have skyrocketed, especially in the U.S. The availability of biosimilars will reduce the cost of insulin and make it possible for more patients with diabetes to reach target HbA1c values."

More information: Satish Garg et al, Efficacy and safety of Biosimilar (SAR342434 insulin lispro) in adults with type 1 diabetes also

using insulin glargine-SORELLA 1 study, *Diabetes Technology & Therapeutics* (2017). DOI: 10.1089/dia.2017.0117