20 YEARS OF EXCELLENCE IN INTERNATIONAL MEETINGS
alliedacademies.com

Joint Event on
2nd WORLD OBESITY CONGRESS
&
International Conference on
DIABETES AND ENDOCRINOLOGY
&
2nd WORLD VACCINES AND IMMUNOLOGY CONGRESS
October 15-16, 2018 | Tokyo, Japan

Agam Shah et al., Biomed Res 2018, Volume 29 | DOI: 10.4066/biomedicalresearch-C5-013

A PROSPECTIVE, OPEN-LABEL, RANDOMIZED, CONTROLLED, MULTI-CENTRE, CLINICAL TRIAL TO EVALUATE THE IMMUNOGENICITY, SAFETY AND EFFICACY OF WOCKHARDT'S BIOSIMILAR INSULIN GLARGINE (GLARITUS®) WITH REFERENCE INSULIN GLARGINE (LANTUS®) IN TYPE 2 DIABETES MELLITUS

Agam Shah[1], Jain R[1], Ajmani AK[2], Sharma SK[3], Mukhopadhyay P[4], Chhaya G[5], Supe PD[6], Pavithran V[7] and Bora H[8]

[1]Wockhardt Ltd., India
[2]BL Kapoor Hospital, India
[3]Diabetes, Thyroid and Endocrine Centre, India
[4]Institute of Post Graduate Medical Education and Research, India
[5]Sanjivani Superspeciality Hospital, India
[6]Supe Heart & Diabetes Hospital and Research Centre, India
[7]KVM Hospital, India
[8]Down Town Hospital, India

Introduction: Insulin glargine provides a peak-less glucose lowering profile and a prolonged duration of action that permits once daily dosing. Biosimilar insulin analogues are compared on immunogenicity, safety and efficacy to the reference biological product.

Objective: Primary objective is to evaluate percent change in anti-insulin antibody [AIA] to glargine in Glaritus® or Lantus® treatment arms from baseline to six months. Secondary objective is to evaluate the change in HbA1c and safety in both arms at six months as well as immunogenic response and safety in Glaritus® arm at 12 months.

Methods: This is a prospective, open-label, randomized, controlled, multi-centre study in 180 type 2 diabetes mellitus (T2DM) patients inadequately controlled on oral hypoglycaemic agents. Eligible patients were randomized to either Glaritus® for 12 months or Lantus® for six months. Treatment was started at 10 units once daily, which was subsequently adjusted according to the subject's glycaemic control. This is an interim analysis of the six months data from the ongoing study.

Results: Out of 90 patients each randomized to Glaritus® and Lantus® arms across 10 sites, 76 (84.4%) and 68 (75.6%) patients completed six months treatment, respectively. There was no significant difference in percent change in AIA titre between the groups at six months (least square [LS] mean difference [95% CI]: 3.4% [-15.1%, 21.9%], p=0.7181). In terms of reduction in HbA1c at six months, the difference between two arms was not significant (LS mean diff [95% CI]: -0.1 [-0.3, 0.1], p=0.2283) and the upper margin of 95% CI was <0.4% (non-inferiority margin). Overall incidence of adverse events was comparable between the groups with intensity being mild (36/37) and outcome resolved (32/37) for most patients.

Conclusion: Glaritus® was found to be non-inferior to Lantus® in glycaemic control and comparable in immunogenic response and safety in T2DM treatment over six months.

BIOGRAPHY

Agam Shah has rich professional experience of nearly 15 years in clinical development, medical affairs and academics. He has been an avid Clinical Research Physician with numerous scientific publication and presentations to his name. He has comprehensive experience of clinical development of biosimilars, complex generics and vaccine products.

ashah@wockhardt.com