

Safety and effectiveness of insulin glargine 300 U/mL in participants with type 2 diabetes who fast during Ramadan in the Gulf region: A subgroup analysis of the real-world ORION study

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Supplementary Material

Table S1. History of diabetes complications and comorbidities

	Participants in ORION study recruited from Gulf region (N = 222)
Any complication or comorbidity	106 (47.7)
≥1 macrovascular complication ^a	23 (10.4)
Diabetic neuropathy	81 (36.5)
Diabetic retinopathy	45 (20.3)
Renal impairment	51 (23.0)
Microalbuminuria	31 (60.8)
Macroalbuminuria	12 (23.5)
Advanced kidney disease	8 (15.7)
Coronary heart disease	21 (9.5)
Myocardial infarction	3 (1.4)
Heart failure	4 (1.8)
NYHA class I	2 (50.0)
NYHA class II	2 (50.0)
Atrial fibrillation	2 (0.9)
Stroke	2 (0.9)
Transient ischemic attack	2 (0.9)
Peripheral vascular disease	3 (1.4)
History of hypoglycemia unawareness	3 (1.4)
History of recurrent hypoglycemia	8 (3.6)

Data presented as n (%)

^aMacrovascular complication included coronary heart disease, myocardial infarction, heart failure, stroke, and transient ischemic attack

N total number of participants, *NYHA* New York Heart Association

Table S2. Hypoglycemia incidence and event rates in all study time periods

Event	<u>Pre-Ramadan</u>			<u>Ramadan</u>			<u>Post-Ramadan</u>		
	All	Daytime	Nocturnal	All	Fasting	Non-fasting	All	Daytime	Nocturnal
Documented symptomatic hypoglycemia (≤ 70 mg/dL)									
<i>n</i> (%)	7 (3.2)	4 (1.8)	3 (1.4)	1 (0.5)	1 (0.5)	0	1 (0.5)	1 (0.5)	0
Event rate	0.018	0.010	0.008	0.005	0.005	0	0.006	0.006	0
Documented symptomatic hypoglycemia < 54 mg/dL									
<i>n</i> (%)	1 (0.5)	1 (0.5)	0	0	0	0	0	0	0
Event rate	0.003	0.003	0	0	0	0	0	0	0

There were no severe hypoglycemia events reported.

Analysis included all eligible participants (N = 222). Event rates are shown as events per participant-month.

Fasting hours were between Suhur and Iftar; non-fasting hours were between Iftar and Suhur.

Appendix – I

Participating physicians from the Gulf region

Country	Investigator name	Role in the Investigation	Institutional Affiliation(s)
Kuwait	Abdulnabi Alattar, MD	Principal Investigator	Amiri Hospital, Kuwait City, Kuwait
	Hisham Mohamady, MD	Principal Investigator	Mubarak Hospital, Jabriya City, Kuwait
	Muneera Al Randi, MD	Principal Investigator	Ministry of Defence Hospital, Kuwait
	Sameer Al Shammari, MD	Principal Investigator	Jahra Hospital, Al Jahra, Kuwait
	Mahmoud Mostafa, MD	Principal Investigator	Amiri Hospital, Kuwait City, Kuwait
	Nabila Al Abdela, PhD	Principal Investigator	Mubarak Hospital, Jabriya, Kuwait
	George Samir, MD	Principal Investigator	Jahra Hospital, Al Jahra, Kuwait
	Nabil Abd EL Hameed, MD	Principal Investigator	Rumaitheya PolyClinic, Rumaitheya City, Kuwait
Qatar	Rayaz A Malik, MD, PhD	Principal Investigator	Weill Cornell Medicine, Doha, Qatar
	Amin Jayyousi, MD	Principal Investigator	HMC, Doha, Qatar
	Tarik Elhadd, MD	Principal Investigator	HMC- Al Wakra Hospital, Doha, Qatar
	Khaled Dukhan, MD	Principal Investigator	HMC- Al Wakra Hospital, Doha, Qatar
	Khalid Shawish, MD	Principal Investigator	HMC- Al Wakra Hospital, Doha, Qatar
Saudi Arabia	Huda Mustafa, MD, PhD	Principal Investigator	AlZafer Hospital, King Abdulaziz Rd, 66261, Najran, Saudi Arabia
	Diaa Ewais, MD	Principal Investigator	Saudi German Hospital, Al Batarji, Alzahra district, 3521, Jeddah, Saudi Arabia
	Ezzat Karima, MD, MSc	Principal Investigator	Hai Al Jamea, Al-Saira Al-Atira St. P.O Box 10153 21433, Jeddah, Saudi Arabia
	Saud Al-Sifri, MD	Principal Investigator	Hada Military Hospital, 3394 Al Hada, 26792, Taif, Saudi Arabia

Country	Investigator name	Role in the Investigation	Institutional Affiliation(s)
	Asim Hassan, MD	Sub-Investigator	Hada Military Hospital, 3394 Al Hada, 26792, Taif, Saudi Arabia
United Arab Emirates	Hans Mohammed, MD	Principal Investigator	Dr Joseph Polyclinic, Dubai, United Arab Emirates
	Mona Salah El Din, MD	Principal Investigator	Garhood Hospital, Dubai, United Arab Emirates
	Dinesh Kumar, MD	Principal Investigator	NMC Speciality Hospital AUH, Abu Dhabi, United Arab Emirates
	Ravi Arora, MD	Principal Investigator	NMC Speciality Hospital AUH, Abu Dhabi, United Arab Emirates
	Manesha Pandey, MD	Principal Investigator	Aster Clinic-Bur Dubai, United Arab Emirates
	Abdul Mohamed Shabeer, MD	Principal Investigator	Modern Family Clinic, Dubai, United Arab Emirates
	Maher Jallo, MD	Principal Investigator	Thumbay Hospital, Ajman City, United Arab Emirates
	Mostafa Abdel Aziz, MD	Principal Investigator	UAQ Hospital, Um al Quain City, United Arab Emirates
	Najiba Abd Al Razaq, MD	Principal Investigator	Kuwait Dubai Hospital, Dubai, United Arab Emirates
	Mahmoud Hammuri, MD	Principal Investigator	Kuwait Dubai Hospital, Dubai, United Arab Emirates
	Yousef Mohammed, MD	Principal Investigator	Al Qassimi hospital, Dubai, United Arab Emirates