

Title: A real-world observational study of Gla-300 in adults with type 2 diabetes who fast during Ramadan in the South Asia region: A subgroup analysis of the ORION study

Authors: Mohamed Hassanein^{1*}, Rakesh Sahay², Mohammad I Hasan³, Arshad Hussain⁴, Vinod Mittal⁵, Riyaz Mohammed⁶, Zaman Shaikh⁷, Faraz Farishta⁸, Senthilnathan Mohanasundaram⁹, Mubarak Naqvi⁹, Arjun Nair⁹, Zubair Ali¹⁰

Affiliations:

¹Dubai Hospital, Dubai Health Authority, Dubai-7272, United Arab Emirates

²Osmania Medical College, Hyderabad, Telangana-500095, India

³Diabetics Institute of Pakistan, Jail Road, Lahore-54000, Pakistan

⁴North West General Hospital, Hayatabad, Peshawar-25100, Pakistan

⁵Delhi Diabetes Care Centre, Sat Nagar, Karol Bagh, Delhi-110005, India

⁶Esani Diabetes and Multispeciality Center, Surya Nagar Colony, Toli Chowki, Hyderabad-500008, Telangana, India

⁷Sir Syed Hospital, Qayyumabad, Karachi-75640, Pakistan

⁸F S Endocrine Centre, Santosh Nagar, Hyderabad-500059, Telangana, India

⁹Sanofi, Mumbai-400072, India

¹⁰Sanofi, Karachi-74900, Pakistan

***Corresponding author:**

Prof. Mohamed Hassanein

Address for correspondence: Dubai Hospital, 222 Al Khaleej Road, Deira, Dubai 7272, United Arab Emirates.

Email: mhassanein148@hotmail.com

Supplementary Table 1. Hypoglycaemia incidence and event rates in all study/time periods

		Pre-Ramadan			Ramadan			Post-Ramadan		
Severe hypoglycaemia and/or documented symptomatic hypoglycaemia ≤ 70 mg/dL	<i>n (%) of patients</i>	1 (0.9)	Daytime	1 (0.9)	1 (0.9)	Fasting	1 (0.9)	0	Daytime	0
			Nocturnal	0		Non-fasting	0		Nocturnal	0
	<i>Event rates (PPM)</i>	0.006	Daytime	0.006	1 (0.01)	Fasting	0.01	0	Daytime	0
			Nocturnal	0		Non-fasting	0		Nocturnal	0
Severe hypoglycaemia and/or documented symptomatic hypoglycaemia < 54 mg/dL	<i>n (%) of patients</i>	1 (0.9)	Daytime	1 (0.9)	0	Fasting	0	0	Daytime	0
			Nocturnal	0		Non-fasting	0		Nocturnal	0
	<i>Event rates (PPM)</i>	0.006	Daytime	0.006	0	Fasting	0	0	Daytime	0
			Nocturnal	0		Non-fasting	0		Nocturnal	0
Severe hypoglycaemia	<i>n (%) of patients</i>	1 (0.9)	Daytime	1 (0.9)	0	Fasting	0	0	Daytime	0
			Nocturnal	0		Non-fasting	0		Nocturnal	0
	<i>Event rates (PPM)</i>	0.006	Daytime	0.006	0	Fasting	0	0	Daytime	0
			Nocturnal	0		Non-fasting	0		Nocturnal	0

N=106. Event rates are shown per participant-month (PPM). Fasting hours lie between Suhur and Iftar; non-fasting hours lie between Iftar and Suhur.

Appendix - I

India			
Investigator last name and first name	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
Mohammed, Riyaz	Investigator	MD, Diploma in Endocrinology (Univ. of South Wales, U.K.)	Esani Diabetes and Multispeciality Center, Plot no.8-1-21/41, Surya Nagar Colony, Towlichowki, Hyderabad-500008, India
Farishta, Faraz	Investigator	MBBS, DNB, MMSc	F S Endocrine Centre, Opp Indo English School, Santosh Nagar, Hyderabad, 500059, India
Farishta, Shaista	Sub-Investigator	MBBS, DCH	F S Endocrine Centre, Opp Indo English School, Santosh Nagar, Hyderabad, 500059, India
Zaidi, Shanehyder	Investigator	MBBS, DNB	Sakshi Diabetic & Medical Centre, Flat No. 102, First, Satya Villa, Opposite High Court, Fate No.6, Ghansi Bazar, Hyderabad-500002, India
Mittal, Vinod	Investigator	MD	Delhi Diabetes Care Centre 5/11791, Sat Nager, Karol Bagh, Delhi-110005, India
Shukla, Rishi	Investigator	MD, DM	Center For Diabetes And Endocrine Disease, C113/14, Shahi Darbar Apartment, Swaroop Nagar, Kanpur – 208002, India
Yalamanchi, S.R.	Investigator	MBBS	Yalamanchi Diabetes Specialities Center, Venkataratnam Street, Dornakkal Road, Suryaraopeta, Governorpeta, Vijayawada, Andhra Pradesh 520002, India
Muppidi, Ravi	Investigator	MBBS	Advanced Endocrinology and Diabetes Hospital and Research Center, Road No. 1, KPHB, Hyderabad, 500072, India

Pakistan			
Investigator last name and first name	Role in the Investigation	Professional Degree(s)	Institutional Affiliation(s)
Hassan, Imtiaz	Principal Investigator	MD, FCPS	Diabetes Institute of Pakistan 71-A Jail Road, Lahore, Pakistan
Mahmud, Regina	Co-Investigator	MD, FCPS	Diabetes Institute of Pakistan 71-A Jail Road, Lahore, Pakistan
Munir, Atif	Principal Investigator	MD, FRCP	Omar Hospital, Service Road, Jail Road, Lahore, Pakistan
Haider, Miqdad	Co-Investigator	MD	Omar Hospital, Service Road, Jail Road, Lahore, Pakistan
Zafar, Jamal	Principal Investigator	MD, FCPS	Hanif Hospital, Saidpur Rd, Block E Asghar Mall Scheme, Rawalpindi, Pakistan
Haider, Hafsa	Co-Investigator	MD	Hanif Hospital, Saidpur Rd, Block E Asghar Mall Scheme, Rawalpindi, Pakistan
Shiekh, Zaman	Principal Investigator	MD, FCPS, FRCP	Sir Syed Hospital, Hospital, Qayyumabad Rd, A - Area Qayyumabad, Karachi 75640, Pakistan
Ayub, Faiza	Co-Investigator	Diploma Diabetes Education	Sir Syed Hospital, Hospital, Qayyumabad Rd, A - Area Qayyumabad, Karachi 75640, Pakistan
Sabir Ali, Sobia	Principal Investigator	MD, FCPS, FRCP	Lady Reading Hospital, Soekarno Rd, Pipal Mandi, Peshawar, Pakistan
Tahir, Hira	Co-Investigator	MSc Nutrition	Lady Reading Hospital, Soekarno Rd, Pipal Mandi, Peshawar, Pakistan
Hussain, Arshad	Principal Investigator	MBBS, MRCPI, FRCPE	North-West General Hospital & Research Center, Phase 5 Hayatabad, Peshawar, Pakistan
Khattak, Almas	Co-Investigator	MD	North-West General Hospital, Passport Office Rd, Phase 5 Hayatabad, Peshawar, Pakistan