

Title page

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Study Design and Baseline Characteristics of Patients with T2DM in the Post-marketing Safety Study of Dulaglutide in China (TRUST-CHN)

Authors

Lixin Guo¹, Li Li², Qiurong Yu³, Na Wang⁴, Jun Chen⁵, Zhiquan Wang⁶, Yuchen Ding⁶

1. Beijing Hospital, National Center of Gerontology, Institute of Geriatric Medicine, Chinese Academy of Medical Science, Beijing
2. Department of Endocrinology, Ningbo First Hospital, Zhejiang
3. Department of Endocrinology, Changshu Second People's Hospital, Jiangsu
4. Department of Endocrinology, Qingdao Endocrine and Diabetes Hospital, Shandong
5. Department of Endocrinology, Xiaoshan Affiliate Hospital of Wenzhou Medical University, Hangzhou
6. Eli Lilly Suzhou Pharmaceutical Co. Ltd, Shanghai

Corresponding Author

Lixin Guo

Beijing Hospital, National Center of Gerontology, Institute of Geriatric Medicine, Chinese Academy of Medical Science, Beijing

Email: glx1218@163.com

Target journal: Diabetes Therapy; <https://www.springer.com/journal/13300/submission-guidelines>

Word limit for ms: No word or figure/table limits for this journal

Supplementary Appendix 1

Table S1. Data collection schedule

	Baseline Visit 1	Post-baseline Visit 2	Post-baseline Visit 3
Timing	Day 0 (pre-dose)	Day 28 (± 7 days; 4 ± 1 weeks)	Day 168 (± 14 days; 24 ± 2 weeks)
Confirmation of eligibility and consent to release information	X		
Demographics	X		
Initial history/pre-existing conditions	X		
Treatment information	X	X	X
Concomitant medications	X	X	X
HbA1c	X		X
Vital signs	X		X
Diabetes Treatment Satisfaction Questionnaire			X
Safety assessments		X	X

Table S2. History of other T2DM treatment – Safety analysis population

	Dulaglutide-experienced N=1047, n (%)	Dulaglutide-naïve N=2247, n (%)	Total N=3294, n (%)
Patients with at least one other previous T2DM treatment	785 (75.0)	1461 (65.0)	2246 (68.2)
Previous T2DM treatments included:			
Insulin	482 (46.0)	832 (37.0)	1314 (39.9)
Metformin	401 (38.3)	697 (31.0)	1098 (33.3)
α -glucosidase inhibitor	233 (22.3)	416 (18.5)	649 (19.7)
Sulfonylurea	164 (15.7)	397 (17.7)	561 (17.0)
GLP-1 RA	165 (15.8)	369 (16.4)	534 (16.2)
DPP-4 inhibitor	162 (15.5)	317 (14.1)	479 (14.5)
SGLT-2 inhibitor	131 (12.5)	225 (10.0)	356 (10.8)
Thiazolidinedione	47 (4.5)	100 (4.5)	147 (4.5)
Number of oral anti-diabetic treatments used for T2DM prior to study entry (i.e. not including insulin and GLP-1 RAs):			
Any	581	1079	1660
=1	237 (22.6)	444 (19.8)	681 (20.7)
=2	199 (19.0)	333 (14.8)	532 (16.2)
≥ 3	145 (13.8)	302 (13.4)	447 (13.6)

DPP-4, dipeptidyl-peptidase-4; GLP-1, glucagon like peptide-1; SGLT, sodium-glucose co-transporter-2; T2DM, type 2 diabetes mellitus; RA, receptor agonists.

Table S3. Dulaglutide treatment history – Safety analysis population

	Dulaglutide-experienced
Total (N)	1047
Duration of previous dulaglutide treatment (days)	
n	1032
Mean (SD)	82.0 (213.7)
Discontinued dulaglutide prior to study entry	
n	24
Duration of previous dulaglutide treatment (days)	
n	20
Mean (SD)	113.8 (101.0)
Last dulaglutide dosage, n (%)	
n	24
0.75 mg	0
1.5 mg	24 (100%)
Last frequency of administration, n (%)	
n	24
Per week	24 (100%)
Dulaglutide ongoing at time of study entry (N)	
n	1012
Duration of previous dulaglutide treatment (days)	
n	1012
Mean (SD)	81.3 (215.3)
Current dulaglutide dosage, n (%)	
n	1012
0.75 mg	2 (0.2%)
1.5 mg	1010 (99.8%)
Current frequency of administration, n (%)	
n	1012
Per week	1011 (99.9%)
Other	1 (0.1%)

N=Total number of patients per category; n=number of patients with available data.

Table S4. Vital signs at baseline – Safety analysis population

	Dulaglutide-experienced N=1047	Dulaglutide-naïve N=2247	Total N=3294
Systolic blood pressure (mmHg)			
n	996	2115	3111
Mean (SD)	130.0 (13.4)	131.1 (14.5)	130.7 (14.2)
Diastolic blood pressure (mmHg)			
n	996	2115	3111
Mean (SD)	82.0 (9.4)	81.4 (10.3)	81.6 (10.1)
Heart rate (bpm)			
n	942	2033	2975

Mean (SD)	81.5 (9.4)	80.8 (10.3)	81.0 (10.0)
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Table S5. Laboratory measurements at baseline – Safety analysis population

	Dulaglutide-experienced N=1047	Dulaglutide-naïve N=2247	Total N=3294
Fasting insulin (mU/L)			
n	218	633	851
Mean (SD)	19.1 (27.5)	20.3 (29.2)	20.0 (28.8)
< LLN, n (%)	8 (3.7%)	12 (1.9%)	20 (2.4%)
Within normal limit, n (%)	164 (75.2%)	448 (70.8%)	612 (71.9%)
> ULN, n (%)	46 (21.1%)	172 (27.2%)	218 (25.6%)
Fasting blood glucose (mmol/L)			
n	317	862	1179
Mean (SD)	8.7 (3.2)	9.3 (3.7)	9.1 (3.6)
< LLN, n (%)	3 (0.9%)	9 (1.0%)	12 (1.0%)
Within normal limit, n (%)	64 (20.2%)	149 (17.3%)	213 (18.1%)
> ULN, n (%)	250 (78.9%)	704 (81.7%)	954 (80.9%)
Fasting C-peptide (ng/mL)			
n	313	769	1082
Mean (SD)	2.5 (1.8)	2.4 (1.6)	2.4 (1.6)
< LLN, n (%)	30 (9.6%)	86 (11.2%)	116 (10.7%)
Within normal limit, n (%)	239 (76.4%)	597 (77.6%)	836 (77.3%)
> ULN, n (%)	44 (14.1%)	86 (11.2%)	130 (12.0%)
2h post-prandial blood glucose (mmol/L)			
n	203	513	716
Mean (SD)	15.6 (5.5)	15.5 (5.4)	15.5 (5.4)
< LLN, n (%)	1 (0.5%)	2 (0.4%)	3 (0.4%)
Within normal limit, n (%)	34 (16.7%)	102 (19.9%)	136 (19.0%)
> ULN, n (%)	167 (82.3%)	399 (77.8%)	566 (79.1%)
Triglycerides (mmol/L)			
n	523	1142	1665
Mean (SD)	2.5 (1.9)	2.8 (3.4)	2.7 (3.0)
< LLN, n (%)	1 (0.2%)	3 (0.3%)	4 (0.2%)
Within normal limit, n (%)	222 (42.4%)	482 (42.2%)	704 (42.3%)
> ULN, n (%)	300 (57.4%)	657 (57.5%)	957 (57.5%)
Total cholesterol (mmol/L)			
n	525	1140	1665
Mean (SD)	6.1 (32.3)	5.0 (2.0)	5.3 (18.2)
< LLN, n (%)	27 (5.1%)	39 (3.4%)	66 (4.0%)
Within normal limit, n (%)	396 (75.4%)	791 (69.4%)	1187 (71.3%)
> ULN, n (%)	102 (19.4%)	310 (27.2%)	412 (24.7%)
Low-density lipoprotein (mmol/L)			
n	493	1117	1610

Mean (SD)	2.7 (1.0)	3.0 (1.0)	2.90 (1.0)
< LLN, n (%)	58 (11.8%)	105 (9.4%)	163 (10.1%)
Within normal limit, n (%)	318 (64.5%)	683 (61.1%)	1001 (62.2%)
> ULN, n (%)	117 (23.7%)	329 (29.5%)	446 (27.7%)
High-density lipoprotein (mmol/L)			
n	491	1113	1604
Mean (SD)	1.1 (0.4)	1.1 (0.3)	1.1 (0.4)
< LLN, n (%)	169 (34.4%)	366 (32.9%)	535 (33.4%)
Within normal limit, n (%)	307 (62.5%)	707 (63.5%)	1014 (63.2%)
> ULN, n (%)	15 (3.1%)	40 (3.6%)	55 (3.4%)
Uric acid (μmol/L)			
n	493	1116	1609
Mean (SD)	844.1 (3146.9)	1237.2 (17751.8)	1116.8 (14885.3)
< LLN, n (%)	11 (2.2%)	24 (2.2%)	35 (2.2%)
Within normal limit, n (%)	366 (74.2%)	766 (68.6%)	1132 (70.4%)
> ULN, n (%)	116 (23.5%)	326 (29.2%)	442 (27.5%)
Blood urea nitrogen (mmol/L)			
n	384	870	1254
Mean (SD)	5.7 (2.5)	5.5 (2.0)	5.6 (2.2)
< LLN, n (%)	12 (3.1%)	22 (2.5%)	34 (2.7%)
Within normal limit, n (%)	333 (86.7%)	772 (88.7%)	1105 (88.1%)
> ULN, n (%)	39 (10.2%)	76 (8.7%)	115 (9.2%)
Creatinine (μmol/L)			
n	498	1124	1622
Mean (SD)	200.8 (1795.7)	91.5 (402.2)	125.1 (1050.4)
< LLN, n (%)	104 (20.9%)	194 (17.3%)	298 (18.4%)
Within normal limit, n (%)	355 (71.3%)	864 (76.9%)	1219 (75.2%)
> ULN, n (%)	39 (7.8%)	66 (5.9%)	105 (6.5%)
Microalbuminuria (mg/dL)			
n	301	687	988
Mean (SD)	18.5 (88.1)	12.7 (46.4)	14.5 (62.2)
< LLN, n (%)	14 (4.7%)	9 (1.3%)	23 (2.3%)
Within normal limit, n (%)	169 (56.1%)	394 (57.4%)	563 (57.0%)
> ULN, n (%)	118 (39.2%)	284 (41.3%)	402 (40.7%)

LLN, lower limit normal; ULN, upper limit normal.

Supplementary Appendix 2

Investigator Site Number	Investigator Name	Ethics Review Board's
		Name and Address
101	Guo, Lixin	EC of Beijing Hospital No.1 Dahua Road, Dongdan, Dongcheng District, Beijing 100730, China
102	Wang, Na	EC of Qingdao Endocrine and Diabetes Hospital No.760 Hefei Road,Shibei District, Qingdao, Shandong 266035, China
103	Li, Shuying	EC of Tian Jin Hospital No. 406 Liberation South Road, Tianjin 300211, China
105	Pan, Tianrong	EC of the 2nd Hspl Affiliated to Anhui Medical Univ. No.678 Furong Road, Economic and Technological Development Zone, Hefei, Anhui 230024, China
106	Li, Honghui	Shenzhen 2nd People's Hospital No3002 Sungang West Rd. Futian District,Gaoming District Foshan, Shenzhen, Gunagdong 518029, China
107	Ma, Zhimin	EC of The Affiliated Suzhou Science and Technology Town Hospital of Nanjing Medical University No.1 Lijiang Road,High-Tech Zone, Suzhou, Jiangsu 215153, China
110	Wang, Jing	EC of Weifang People Hospital No152,Guangwen Street,Weifang, Shandong 261041, China
111	Chen, Jun	EC of Hangzhou Xiaoshan 1st Hospital No199 South Shixin Rd,Xiaoshan District, Hangzhou, Zhejiang 312000, China
113	Li, Li	EC of Ningbo First Hospital 31 Guangji Street, Haishu district, Ningbo, Zhejiang 315174, China
116	Cui, Wei	Ethics Committee of The First Affiliated Hospital of Xi'an Jiaotong University No. 277 Yanta West Road, Xi'an, Shanxi 710061, China
117	Ye, Jianhua	The First Affiliated Hospital of Guangdong College of Pharmacy No. 19 Nonglinxia Rd, Guangzhou, Gunagdong 510080, China
120	Xiao, Xinhua	EC of The First Affiliated Hospital of University of South China No. 69 Chuanshan Rd., Hengyang, Hu'nan 421001, China
121	Li, Xuefeng	EC of Taihe Hospital No.32 Renminnan Road, Shiyan, Hubei 442000, China
122	Yu, Qiurong	EC of Changshu No.2 People's Hospital No.68 Haiyu south road, Changshu, Jiangsu 215500, China
125	Chen, Hong	EC of Zhujiang Hospital of Southern Medical University No253 Mid of Gongye Avenue,Zhenjiang District, Guangzhou, Guangdong 510280, China
128	Wang, Wenbo	EC of Peking University Shougang Hospital No.9 Jinyuanzhuang Road, Shijingshan District, Beijing 100144, China

131	Wu, Jun	EC of Wuhan Third Hospital No.241, Pengliuyang Road,Wuchang District, Wuhan, Hubei 430060, China
132	Gu, Yunjuan	EC of Affiliated Hospital of Nantong University No. 20 Xisi Road, Nantong, Jiangsu 226001, China
133	Liu, Shiwei	Taiyuan Central Hospital No.1,Dongsandao Lane, Taiyuan, Shanxi 030009, China
134	Yang, Jing	EC of The 1st Affiliated Hospital of Shanxi Medical University Medical technology building, First Floor,No85, Jiefang South Rd. Taiyuan, Shanxi 030001, China
135	Song, Bing	EC of The First Hospital affiliated to Liaoning Medical college No. 2 Wuduan Renmin Street,Guta District, Jinzhou, Liaoning 121001, China
140	Rao, Xiaopang	Clinical Trial Ethic Committee of Qingdao Chengyang District People's Hospital No 600, Changcheng road,Chengyang District, Qingdao, Shandong 266100, China
145	Chen, Libo	EC of Shenzhen People's Hospital No.1017 Dongmen North Rd, Shenzhen, Guangdong 518020, China
146	Zhang, Wei	The Second Affiliated Hospital of Xingtai Medical College No.618, Steel North Road, Xingtai, Hebei 054000, China
147	Guo, Qian	EC of Gansu Province People Hospital No.204 Donggang West Road, Chengguan District, Lanzhou, Gansu 730000, China
148	Ding, Hongcheng	EC of Shiyan people's Hospital No.39, Chaoyangzhong Road, Shiyan, Hubei 442000, China
149	Zhao, Fan	Jiangmen People's Hospital No127 Gaodili Penglai Rd. Jiangmen, Guangdong 529020, China
150	Wang, Lijun	Institutional Ethics Committee of Taizhou First People's Hospital No. 218 Hengjie Road, Huangyan District, Taizhou, Zhejiang 318020, China
153	Zhao, Dong	EC of Beijing Luhe Hospital, Capital Medical University No.82 Xinhua South Road, Tongzhou District, Beijing 101100, China
155	Hu, Shuguo	Clinical Trial Ethics Committee of Shijiazhuang 2nd Hospital No53,Hauxi Rd, Shijiazhuang, Hebei 050051, China
157	Jiao, Xuehua	Clinical Medical Trial Ethics Committee of Suzhou Ninth People's Hospital No. 2666 Ludang Road, Wujiang District, Suzhou, Jiangsu 215200, China
158	Mao, Yushan	EC of The Affiliated Hospital of Medical School of Ningbo University No. 247 Renmin Road, Jiangbei District, Ningbo, Zhejiang 315207, China

104	Zhang, Chi	EC of People's Hospital of Hunan Province No.61, Jiefang Xi Road, Changsha, Hunan 410002, China
109	Fu, Yanqin	EC of Zhengzhou University Affiliated 2nd Hospital No.2 Jingba Rd. Zhengzhou, Henan 450014, China
114	Li, Ling	EC of Zhong Da Hospital, Southeast University No.87 Dingjiaqiao, Gulou District, Nanjing, Jiangsu 210009, China
123	Duan, Binhong	EC of Heilongjiang Provincial Hospital (Nanshang) No. 82 Zhongshan Road, Harbin, Heilongjiang 150036, China
126	Duan, Junting	EC of Beijing civil aviation General Hospital No1,Gaojingjia ,Outside Chaoyangmen, Beijing 100025, China
127	Huang, Wei	EC of Beijing Haidian Hospital No. 29 Zhongguancun Street, Beijing 100080, China
129	Zhou, Yanhong	EC of Xinxiang Central Hospital Xinxiang Central Hospital, Xinxiang, Henan 453000, China
137	Deng, Wuquan	EC of No.4 People's Hospital of Chongqing No.1, Jiankang Road, Chongqing 400014, China
141	Yang, Zhixia	EC of Langfang People's Hospital No.37 Xinhua Road, Langfang, Hebei 065000, China
143	Wang, Suijun	EC of Shanghai Shidong Hospital No.999, Shiguang Road, Shanghai 200438, China
108	Guo, Kunquan	EC of Shiyan General Hospital of Dongfeng motor 16 Daling Road, Zhangwan District,Shiyan, Hubei 442008, China
115	Wang, Kun	EC of Nanjing Jiangning Hospital No. 169, Hushan Road, Jiangning District, Nanjing, Jiangsu 211100, China
124	Yu, Xuebing	EC of Changzhou Jintan District People's Hospital 500 Jintan Avenue, Jintan District, Changzhou, Jiangsu 213200, China
138	Xi, Yue	EC of The Third Affiliated Hospital of Jinzhou Medical University No 2, Section 5, Heping Road, Linghe District, Jingzhou, Liaoning 121001, China