

World Health Organization Trial Registration Data Set

Data category	Information
1. Primary Registry and Trial Identifying Number	ClinicalTrials.gov Identifier: NCT05015283
2. Date of Registration in Primary Registry	27 February 2022
3. Secondary Identifying Numbers	None
4. Source(s) of Monetary or Material Support	Beijing Municipal Science & Technology Commission (Z211100002921029), National Key Technologies R&D Program (2015BAI13B09), Beihune Charitable Foundation (DXWKYJ001), and Beijing Excellent Talents Training Funding Program (2018000021469G195)
5. Primary Sponsor	Beijing Friendship Hospital, Capital Medical University
6. Secondary Sponsor(s)	None
7. Contact for Public Queries	Peng Zhang
8. Contact for Scientific Queries	Peng Zhang
9. Public Title	Diabetes remission in obese subjects with type 2 diabetes after one anastomosis gastric bypass or Roux-en-Y gastric bypass: a multicenter, randomized controlled, open-label, superiority trial-ORDER trial
10. Scientific Title	Efficacy and safety of one anastomosis gastric bypass versus Roux-en-Y gastric bypass for type 2 diabetes Remission (ORDER): protocol of a multicenter, randomized controlled, open-label, superiority trial
11. Countries of Recruitment	China, or and Singapore
12. Health Condition(s) or Problem(s) Studied	Type 2 diabetes and obesity
13. Intervention(s)	one anastomosis gastric bypass and Roux-en-Y gastric bypass
14. Key Inclusion and Exclusion Criteria	<p>Inclusion criteria</p> <ul style="list-style-type: none"> ① Age 21–65 years (both sexes) ② BMI 27.5–50 kg/m² ③ Previously diagnosed T2D duration ≥6 months ④ HbA1c ≥7.0%. ⑤ Currently receiving oral/injectable antidiabetic medications [insulin/ Glucagon-like peptide-1 (GLP-1) receptor agonists] ⑥ OAGB/RYGB recommended by a multidisciplinary team <p>Exclusion criteria</p> <ul style="list-style-type: none"> ① Active gastrointestinal ulcer ② Latent autoimmune diabetes in the adult or type 1 diabetes (Reviewer #1, comment #2) ③ Current Helicobacter pylori infection ④ Currently diagnosed with severe gastroesophageal

	<p>reflux disease by esophagogastroduodenoscopy (EGD) defined as Los Angeles classification grade >B or Barrett's esophagus</p> <p>⑤ History of major abdominal surgery including bariatric surgery (except appendectomy and gynecological procedures)</p> <p>⑥ History of serious cardiovascular/cerebrovascular diseases</p> <p>⑦ History of liver cirrhosis (Child-Pugh \geqA)</p> <p>⑧ History of chronic kidney disease (estimated glomerular filtration rate) <60 mL/min/1.73 m²)</p> <p>⑨ History of inflammatory bowel disease (including ulcerative colitis and Crohn's disease)</p> <p>⑩ History of chronic anemia (Hgb level <100 g/L in men and <90 g/L in women)</p> <p>⑪ Simultaneous surgery for cholecystectomy</p> <p>⑫ Pregnancy or desire for conception during the first year of the study period</p> <p>⑬ Uncontrolled mental and psychological disorders</p> <p>⑭ Expected survival <5 years due to end-stage disease or malignant tumor</p> <p>⑮ Participation in clinical studies/trials with conflicting interest with this study</p> <p>⑯ Unwilling or unable to provide informed consent</p>
15. Study Type	<p>Interventional</p> <p>Allocation: randomised</p> <p>Intervention model: Parallel assignment</p> <p>Masking: none</p> <p>Primary purpose: treatment</p>
16. Date of First Enrollment	6 May, 2022
17. Sample Size	248
18. Recruitment Status	Recruiting: participants are currently being recruited and enrolled
19. Primary Outcome(s)	The only primary endpoint is the rate of complete diabetes remission which is defined as HbA1c \leq 6.0% (42 mmol/mol) and fasting plasma glucose \leq 5.6 mmol/l without any antidiabetic medications at 1 year after surgery.
20. Key Secondary Outcomes	<ul style="list-style-type: none"> ● HbA1c ● Fasting and stimulated levels of plasma glucose, insulin, and C-peptide ● Use of antidiabetic medication ● The remission rate of microalbuminuria, ● The progression rate of diabetic retinopathy (DR) ● Body weight, BMI, waist and hip circumference

	<ul style="list-style-type: none"> ● Excess and total BMI loss percentage, excess and total weight loss percentage, and absolute weight loss (kg). The above outcome measures are calculated based on the optimal BMI (25 kg/m²). ● Resting systolic and diastolic blood pressure ● Use of anti-hypertensive medication ● Fasting plasma lipid profile ● Use of lipid-lowering drugs ● Echocardiography ● Cervical vessels and lower extremity vascular ultrasound ● Major Adverse Cardiovascular Events (MACE) events ● The American Diabetes Association composite triple end point ● Gastro-oesophageal reflux disease ● Self-reported gastrointestinal symptoms ● Gastric and esophageal mucosa modifications as demonstrate by EGD and the following biopsy pathology ● Hemoglobin ● Albumin, prealbumin ● Folic acid, ferritin, saturation coefficient, vitamin B12 ● Parathyroid hormone (PTH), vitamin D ● Quality of life ● Surgical and medical complications (Dindo-Clavien classification) ● Hypoglycaemic episodes and dumping syndrome (Sigstad questionnaire) ● Length of hospitalization ● Readmissions
21. Ethics Review	<p>Status:Approved</p> <p>Date of approval:25 January 2022</p> <p>Name and contact details of Ethics committee(s): Beijing Friendship Hospital, Capital Medical University (2021-P2-037-03)</p>
22. Completion date	Not yet
23. Summary Results	Not yet
24. IPD sharing statement	<ol style="list-style-type: none"> 1. Will individual deidentified participant data (including data dictionaries) will be shared: Yes 2. what data in particular will be shared: Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices). 3. what other documents will be available: study protocol

	<p>4. when will data be available (start and end dates): Beginning 6 months and ending 24 months following article publication.</p> <p>5. With whom: Investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose.</p> <p>6. For what types of analysis: For individual participant data meta-analysis.</p> <p>7. By what mechanism will data be made available: Proposals should be directed to zhangzht@ccmu.edu.cn to gain access, data requestors will need to sign a data access agreement.</p>
--	---