INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest: **No.**

Effect of roux-en Y gastric bypass surgery on patients with type 2 diabetes mellitus: a protocol of systematic review and meta-analysis

Chen, KY[1]; Liu, YL[2]; Shang, JC[3]; Su, DW[4]; Yao, RR[5]; Ke, DZ[6]; Tian, H[7].

Review question / Objective: **Can roux-en Y gastric bypass surgery (RYGBS) effectively treat type 2 diabetes mellitus (T2DM)?**
Condition being studied: **type 2 diabetes mellitus; roux-en Y gastric bypass surgery.**
Information sources: **Search electronic databases In this study, we will search the following databases of MEDILINE, EMBASE, CENTRAL, CINAHL, AMED, and CNKI. All these databases will be searched from inceptions to March 31, 2020. All those databases will be searched with no restrictions of language and publication status. We will include randomized controlled trials (RCTs) on evaluating the effect of RYGBS for patients with T2DM. We will build an example of detailed search strategy for MEDLINE . We will also adapt similar search strategies to any other electronic databases. Search for other resources In addition, we will also search conference abstracts, dissertations, and reference lists of associated reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 April 2020 and was last updated on 21 April 2020 (registration number INPLASY202040127.

INTRODUCTION

Review question / Objective: **Can roux-en Y gastric bypass surgery (RYGBS) effectively treat type 2 diabetes mellitus (T2DM)?**

Condition being studied: **type 2 diabetes mellitus; roux-en Y gastric bypass surgery**

METHODS

Participant or population: **Participants who were clinically diagnosed as T2DM will be included without limitations of gender, age, economic status, and educational background.**

Intervention: **In the experimental group, all participants received RYGBS intervention.**

Comparator: In the control group, all participants who received any other interventions, except RYGBS will be included.

Study designs to be included: All randomized controlled trials (RCTs) on the effect of RYGBS for patients with T2DM will be included.

Eligibility criteria: All RCTs on the effect of RYGBS for patients with T2DM will be included without any language or publication restrictions. However, any other studies, except RCTs will not be included.

Information sources: Search electronic databases In this study, we will search the following databases of MEDILINE, EMBASE, CENTRAL, CINAHL, AMED, and CNKI. All these databases will be searched from inceptions to March 31, 2020. All those databases will be searched with no restrictions of language and publication status. We will include randomized controlled trials (RCTs) on evaluating the effect of RYGBS for patients with T2DM. We will build an example of detailed search strategy for MEDLINE . We will also adapt similar search strategies to any other electronic databases. Search for other resources In addition, we will also search conference abstracts, dissertations, and reference lists of associated reviews.

Main outcome(s): The primary outcomes include partial remission of T2DM (defined as blood HbA1c < 6.5 % (48 mmol/mol)), and complete remission of T2DM (defined as blood HbA1c <6 % (42 mmol/mol)). The secondary outcomes consist of hemoglobin A1c, body mass index, lipids, high sensitivity C-reactive protein, tumor necrosis factor-α, and high molecular weight adiponectin.

Data management: Two authors will independently extract data from the included studies based on the standardized data collection form. Any different opinions between two authors will be solved and discussed by a third author. Extracted data consist of title, first author, publication year, study characteristics, patient characteristics, study setting, inclusion and exclusion criteria, diagnostic criteria, study design, details of interventions and controls, outcome assessments, safety, and funding information.

Quality assessment / Risk of bias analysis: Two authors will independently assess the risk of bias using Cochrane Risk of Bias Tool, which was developed to assess the methodological quality. Using this tool, all risk of bias will be divided as low, unclear or high risk of bias. Any divergences between two authors will be worked out by a third author through discussion.

Strategy of data synthesis: We will use RevMan 5.3 software for statistical analysis in this study. We will present dichotomous data using risk ratio and 95% confidence intervals (CIs). We will show the continuous data using mean difference or standardized mean difference and 95% CIs. We will utilize the I^2 statistic test to identify heterogeneity among included studies. The value of I^2 ≤50% means reasonable heterogeneity, and we will use a fixed-effect model. We will undertake meta-analysis if sufficient data on the similar characteristics of study and patient, interventions, controls, and outcomes are obtained. On the hand other, the value of I^2 > 50% shows obvious heterogeneity, and we will utilize a random-effect model. Additionally, we will also perform subgroup analysis to investigate any factor that may result in such significant heterogeneity.

Subgroup analysis: Subgroup analysis will be undertaken based on the different types of interventions and control therapies, and outcome assessments.

Sensibility analysis: Sensitivity analysis will be performed to explore the stability of the pooled outcome results by removing low quality studies.

Country(ies) involved: China.

Keywords: Type 2 diabetes mellitus; roux-en Y gastric bypass surgery; effect.