INPLASY PROTOCOL

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

Conflicts of interest: **None.**

Efficacy of laparoscopic sleeve gastrectomy in obese patients with type 2 diabetes mellitus: a protocol of systematic review and meta-analysis

Wei, WW[1]; Fu, XD[2]; Su, DW[3]; Ke, DZ[4]; Yao, RR[5]; Chen, KY[6]; Tian, H[7].

Review question / Objective: **Can laparoscopic sleeve gastrectomy (LSGT) effectively treat obese patients (OP) with type 2 diabetes mellitus (T2DM)?**
Condition being studied: **type 2 diabetes mellitus and laparoscopic sleeve gastrectomy.**
Information sources: **Search electronic databases The trials published will be carried out in electronic databases from inception to the March 31, 2020, which consist of PubMed, EMBASE, Cochrane Library, Scopus, Web of Science, CINAHL, AMED, WANGFANG, VIP and CNKI. We will not apply any limitations to the language and publication status. The detailed search strategy for PubMed is presented. Identical search strategies for other electronic databases will also be created. Search for other resources Besides, we will also search other sources to avoid missing any potential trials, such as conference abstracts, dissertations, and reference lists of related 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 INPLASY202040128.

INTRODUCTION

Review question / Objective: **Can laparoscopic sleeve gastrectomy (LSGT) effectively treat obese patients (OP) with type 2 diabetes mellitus (T2DM)?**

Condition being studied: **type 2 diabetes mellitus and laparoscopic sleeve gastrectomy.**

METHODS

Participant or population: **Any participants who were clinically diagnosed as OP with**

T2DM will be considered for inclusion regardless their nationality, race, sex, and age.

Intervention: All participants in the experimental group received any forms of LSGT intervention.

Comparator: In the control group, we will include participants who underwent any managements, but not LSGT.

Study designs to be included: This study will include randomized controlled trials (RCTs) alone that focusing on the efficacy and complications of LSGT for the management of OP.

Eligibility criteria: This study will include RCTs alone that focusing on the efficacy and complications of LSGT for the management of OP with T2DM. We will exclude any other studies, such as animal studies, case reports, case series, reviews, comments, non-clinical trials, non-controlled trials, and quasi-RCTs.

Information sources: Search electronic databases The trials published will be carried out in electronic databases from inception to the March 31, 2020, which consist of PubMed, EMBASE, Cochrane Library, Scopus, Web of Science, CINAHL, AMED, WANGFANG, VIP and CNKI. We will not apply any limitations to the language and publication status. The detailed search strategy for PubMed is presented. Identical search strategies for other electronic databases will also be created. Search for other resources Besides, we will also search other sources to avoid missing any potential trials, such as conference abstracts, dissertations, and reference lists of related reviews.

Main outcome(s): The primary outcome is complete remission of T2DM (defined as blood hemoglobin A1C (HbA1c) <6 % (42 mmol/mol)). The secondary outcomes are body mass index, partial remission of T2DM (defined as blood HbA1c < 6.5 % (48 mmol/mol)), lipids, high sensitivity C-reactive protein, quality of life (measured as any relevant scales), and complications.

Data management: Two authors will independently perform data extraction according to the predefined standard data extraction sheet. If any different opinions occur between two authors, we will ask for a third author help to make consistent decision. The extracted information comprises of study basic information (such as title, authors, year of publication), study population, sample size, eligibility criteria, diagnostic criteria, randomization, blind, interventions, comparators, outcomes, safety, follow-up information, funding, conflict of interest and any other relevant details.

Quality assessment / Risk of bias analysis: Risk of bias assessment will be evaluated by two independent authors using Cochrane Risk of Bias Tool for RCTs, which comprises of 7 aspects. Three different grades (high risk of bias, unclear risk of bias, and low risk of bias) will be utilized to check each aspect for all included RCTs. Any discrepancies between two authors will be resolved by a third author through discussion.

Strategy of data synthesis: We will apply RevMan 5.3 software to carry out statistical analysis. Dichotomous variables such as incidence of complications will be presented as risk ratio and 95% confidence intervals (CIs). Continuous variables such as complete remission of T2DM, body mass index, partial remission of T2DM, lipids, high sensitivity C-reactive protein, and quality of life will be calculated as mean difference or standardized mean difference and 95% CIs. Heterogeneity will be checked using I^2 statistic test. $I^2 \leq 50\%$ will be regarded as low heterogeneity, and a fixed-effect model will be applied for data pooling. In addition, when necessary, meta-analysis will be conducted if sufficient data on the similar characteristics of study and participant, interventions, comparators, and outcomes are obtained. $I^2 > 50\%$ will be considered as obvious heterogeneity and a random-effect model will be utilized. Additionally, we will undertake subgroup analysis to investigator possible causes for obvious heterogeneity. If there is still obvious heterogeneity after subgroup

analysis, we will not pool the data, and a narrative synthesis of findings will be conducted. We will compare each outcome in OP with T2DM between patients who received LSGT and those who did not. In case of missing essential data from included trials, we will try our best to obtain it by contacting primary study authors. When it is not possible, we will discuss its potential impacts of missing data on the results.

Subgroup analysis: We will run a subgroup analysis according to the different study characteristics, population characteristics, details of interventions and comparators, and outcome measurements.

Sensibility analysis: We will carry out sensitivity analysis to identify the stability and robustness of the findings by excluding trials with high risk of bias.

Country(ies) involved: China.

Keywords: Type 2 diabetes mellitus; laparoscopic sleeve gastrectomy; efficacy.