INPLASY PROTOCOL

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Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

Efficacy of polyethylene glycol loxenatide for type 2 diabetes mellitus patients: A systematic review and meta-analysis

Liu, YB[1]; Zhang, Z[2]; Yu, SH[3]; Zhang, ZW[4].

Review question / Objective: **The aim of the study is to evaluate the efficacy of polyethylene glycol loxenatide alone or along with other conventional hypoglycemic drugs for type 2 diabetes mellitus patients compared with placebo or other conventional hypoglycemic drugs comprehensively.**
Condition being studied: **Type 2 diabetes mellitus, the most prevalent diabetes, accounts for more than 90% diabetic patients. T2DM is a metabolic disease induced by a variety of causes. It would lead to insulin deficiency, insulin resistance, and persistently elevated blood glucose levels. Some studies have proved that polyethylene glycol loxenatide has significant effect of on the control of blood glucose in patients with type 2 diabetes mellitus, but there is some controversy over the improvement of blood lipids and body weight, and more evidences are needed to verify such effect and provide a reference for clinical treatment.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 May 2023 and was last updated on 28 May 2023 (registration number INPLASY202350106).

INTRODUCTION

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METHODS

Participant or population: Patients with type 2 diabetes mellitus.

Intervention: Polyethylene glycol loxenatide alone or along with other conventional hypoglycemic drugs.

Comparator: Placebo or other conventional hypoglycemic drugs.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: The exclusion criteria are shown as follows: the study design was scientific research achievements, systematic reviews, and animal experiments; trials that did not report related information; the full text could not be obtained.

Information sources: PubMed, Cochrane Library, Embase, China National Knowledge Infrastructure, China Scientific Journal, Wanfang Data, and SinoMed databases.

Main outcome(s): Blood glucose: glycosylated hemoglobin, fasting plasma glucose, 2-hour postprandial blood glucose, Blood lipid profiles: total cholesterol, triglycerides, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol. Body mass index and body weight.

Quality assessment / Risk of bias analysis: Two review authors will independently assess the risk of bias in included studies by considering the following characteristics: Randomisation sequence generation: was the allocation sequence adequately generated? Treatment allocation concealment: was the allocated treatment adequately concealed from study participants and clinicians and other healthcare or research staff at the enrolment stage? Blinding: were the personnel assessing outcomes and analysing data sufficiently blinded to the intervention allocation throughout the trial? Completeness of outcome data: were participant exclusions, attrition and incomplete outcome data adequately addressed in the published report? Selective outcome reporting: is there evidence of selective outcome reporting and might this have affected the study results? Other sources of bias: was the trial apparently free of any other problems that could produce a high risk of bias? Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with involvement of a third review author where necessary.

Strategy of data synthesis: RevMan 5.3 software is used for data analysis. Mean difference (MD) and 95% confidence intervals (CI) are used to represent continuous variables. $P<0.05$ is considered statistically significant. The statistical heterogeneity is evaluated by Chi-square and I2 tests. The results of non-heterogeneous ($I2<50\%$) and heterogeneous ($I2>50\%$) are analyzed by fixed or random effects models for calculating the pooled effect, respectively.

Subgroup analysis: Subgroup analysis is performed based on different intervention measures, dosages and treatment time.

Sensitivity analysis: Sensitivity analysis is performed in RevMan 5.3 software by removing a trial at a time.

Country(ies) involved: China.

Keywords: Polyethylene glycol loxenatide, type 2 diabetes mellitus, blood glucose, blood lipid profiles, body mass index, body weight, meta-analysis.

Contributions of each author:

Author 1 - Yibo Liu - YBL contributed to analysis of data, literature review and preparation of the manuscript.
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