

Triple Drug Fixed Dose Combination Of Sodium-Glucose Co-transporter 2 Inhibitor, Dipeptidyl Peptidase-4 Inhibitor And Metformin In Type 2 Diabetes In India: A Systematic Review With Meta-Analysis

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ADMINISTRATIVE INFORMATION**Support** - No external financial support was sought.**Review Stage at time of this submission** - Preliminary searches.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202430022**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 March 2024 and was last updated on 06 March 2024.**INTRODUCTION**

Review question / Objective P = Patients with type 2 diabetes. I = Triple fixed dose combination of dapagliflozin, sitagliptin, and metformin (in a single pill). C = Sitagliptin and metformin. O = Differences in mean HBA1c, fasting & PP sugar. Adverse effects of interest.

Rationale Multiple drugs are required for management of Type 2 Diabetes leading to a loss of compliance and subsequent loss of metabolic control. The aim of this meta-analysis is to evaluate the effectiveness of single pill fixed dose combinations in achieving metabolic control, thereby improving compliance and metabolic health in the long run.

Condition being studied Type 2 Diabetes.

METHODS

Search strategy The Cochrane library and Google scholar will be systematically searched for relevant citations.

Participant or population Type 2 Diabetes patients above 18 years of age.

Intervention Fixed dose single dose triple combination of dapagliflozin, sitagliptin, and metformin.

Comparator A combination of sitagliptin and metformin.

Study designs to be included Only randomised controlled trials would be included for analysis.

Eligibility criteria 1. Type 2 diabetes. 2. Age above 18 years. 3. Randomised controlled trials. 4. A minimum of 12 weeks follow up.

Information sources Cochrane library, Google scholar, conference papers and abstracts.

Main outcome(s) 1. HBA1c. 2. Fasting plasma glucose. 3. Post prandial glucose.

Additional outcome(s) Adverse effects on interest: 1. Therapy related total adverse events. 2. Hypoglycaemia.

Quality assessment / Risk of bias analysis Cochrane risk of bias algorithm.

Strategy of data synthesis 1. Random effects model meta-analysis. 2. Effect size: Mead difference. 3. Assessment of heterogeneity with prediction interval and Q statistics.

Subgroup analysis Will be attempted faced with significant heterogeneity in the pooled effect size.

Sensitivity analysis Leave one out sensitivity analysis will be performed to rule out significant outliers.

Language restriction English language.

Country(ies) involved India.

Keywords Type 2 diabetes, fixed dose combination, meta-analysis, HBA1C.

Contributions of each author

Author 1 - SAMIT GHOSAL - Conceptualised the study and plan to perform the meta-analysis.

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