INPLASY PROTOCOL

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None declared.

Once-Weekly Insulin Icodec vs Once-Daily Insulin Glargine U100 for Type 2 Diabetes: A Meta-analysis of Phase 2 Randomized Controlled Trials

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Review question / Objective: **To compare Once-Weekly Insulin Icodec and Once-Daily Insulin Glargine U100 in patients with Type 2 Diabetes Mellitus using oral hypoglycemic drugs in need of insulin therapy.**
Condition being studied: **Patients with Diabetes Mellitus Type 2 using oral hypoglycemic drugs in need for basal insulin.**
Eligibility criteria: **Inclusion in this meta-analysis was restricted to studies that met all the following criteria: (1) randomized trials; (2) comparing the use once weekly insulin icodec to once daily insulin glargine; (3) enrolling patients with type 1 or type 2 diabetes mellitus; (4) evaluating any of the desired outcomes; (4) articles in written on english language. We excluded studies with (1) no control group; (2) overlapping studies population; clinical trial register entry only; (3) non-human studies and (4) studies reported only as abstracts.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 May 2022 and was last updated on 16 May 2022 (registration number INPLASY202250102).

INTRODUCTION

Review question / Objective: **To compare Once-Weekly Insulin Icodec and Once-Daily Insulin Glargine U100 in patients with Type 2 Diabetes Mellitus using oral hypoglycemic drugs in need of insulin therapy**

Condition being studied: **Patients with Diabetes Mellitus Type 2 using oral hypoglycemic drugs in need for basal insulin.**

METHODS

Search strategy: **"Icodec".**

Participant or population: Patients with TDM2.

Intervention: Once-Weekly Insulin Icodec.

Comparator: Once-Daily Insulin Glargine U100.

Study designs to be included: Phase 2 Randomized Controlled Trials.

Eligibility criteria: Inclusion in this meta-analysis was restricted to studies that met all the following criteria: (1) randomized trials; (2) comparing the use once weekly insulin icodec to once daily insulin glargine; (3) enrolling patients with type 1 or type 2 diabetes mellitus; (4) evaluating any of the desired outcomes; (4) articles in written on english language. We excluded studies with (1) no control group; (2) overlapping studies population; clinical trial register entry only; (3) non-human studies and (4) studies reported only as abstracts.

Information sources: PubMed, Embase and Cochrane central register of controlled trials.

Main outcome(s): Diabetes Control (Time in Range, Fasting Plasma Glucose, Glycated Hemoglobin, Body Weight, Insulin Dose Difference).

Additional outcome(s): Safety Endpoints (Any adverse outcome, Injection Site Reaction, Hypersensitivity Reaction, Hypoglycemic alert, Clinically significant or severe hypoglycemia).

Quality assessment / Risk of bias analysis: We will evaluate the risk of bias in randomized studies using version 2 of the Cochrane Risk of Bias assessment tool. Two independent authors will complete the risk of bias assessment (R.R.S and J.O.N.S). Disagreements will be resolved through a consensus after discussing reasons for discrepancies.

Strategy of data synthesis: Odds-ratios (OR) with 95% confidence intervals will be used to compare treatment effect for categorical endpoints. Continuous outcomes will be compared with mean differences. We will assess heterogeneity with I^2 statistics and Cochran Q test; p-values 25% will be considered significant for heterogeneity. We will use a fixed-effect model for outcomes with low heterogeneity (I^2<25%). Otherwise, a DerSimonian and Laird random-effects model will be used. Review Manager 5.3 (Cochrane Center, The Cochrane Collaboration, Denmark) will be used for statistical analysis.

Subgroup analysis: There will be no subgroup analysis.

Sensitivity analysis: There is no sensitivity analysis planned.

Language: Articles written on english language.

Country(ies) involved: Brazil.

Keywords: Diabetes Mellitus, Type 2. Insulin; Insulin Long-Acting; Insulin Glargine; Insulin Icodec; Glycemic Control; Glycated Hemoglobin A; Hypoglycemia.

Contributions of each author:

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