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INPLASY

Efficacy and Safety of Direct-Acting Antiviral Regimens for Hepatitis C Virus Infection: Protocol for A Network Meta-Analysis

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ADMINISTRATIVE INFORMATION

Support - Taiwan Society of Ultrasound in Medicine.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 November 2024 and was last updated on 13 November 2024.

INTRODUCTION

Review question / Objective This study aims to compare the relative efficacy and safety of direct-acting antiviral (DAA) regimens for hepatitis C virus (HCV) infection across various genotypes and patient profiles.

Rationale HCV infection remains a global health issue, with DAA regimens dramatically improving patient outcomes through high sustained virologic response (SVR) rates. However, there is limited clarity on the comparative effectiveness and safety of different DAA regimens, particularly across various genotypes and patient conditions. This network meta-analysis addresses this gap by directly comparing multiple DAA combinations to guide optimal treatment selection.

Condition being studied The PICO (population, intervention, comparison, outcome) framework for this meta-analysis includes: Population (P): Human participants with HCV ; Intervention (I): DAA regimens; Comparison (C): Other DAA regimens, PegIFN/Ribavirin, or placebo ; Outcomes (O): Sustained virologic response at 12 weeks (SVR12) and serious adverse events.

METHODS

Search strategy Independent electronic searches by two authors in databases including PubMed, Cochrane Library, Embase, ClinicalTrials.gov, and Web of Science, using keywords such as ('hepatitis C' AND 'direct-acting antiviral' AND specific DAA drug names).

Participant or population Human participants with HCV infection.

Intervention DAA regimens.

Comparator Other DAA regimens, PegIFN/Ribavirin, or placebo.

Study designs to be included Randomized controlled trials (RCTs).

Eligibility criteria (1) RCTs involving HCV patients across any genotype or cirrhosis status; (2) At least one DAA treatment arm; (3) Outcomes including SVR12 and/or serious adverse events.

Information sources Searches in PubMed, Cochrane Library, Embase, ClinicalTrials.gov, and Web of Science.

Main outcome(s) The primary outcomes will be sustained virologic response at 12 weeks (SVR12) and the incidence of serious adverse events. Secondary outcomes will include treatment efficacy across different DAA regimens and the comparative safety profiles.

Data management Data extraction by two independent authors, capturing outcomes, study design, DAA regimen details, and patient demographics. Consistency checks on scales and measures were performed to ensure accuracy.

Quality assessment / Risk of bias analysis The Cochrane risk of bias tool for randomized trials (RoB 2) assesses randomization, adherence, outcome measurement, missing data, selective reporting, and overall bias.

Strategy of data synthesis This analysis is performed using MetaInsight (version 6.1.0; Complex Reviews Support Unit, National Institute for Health Research, London, UK), which operates within a frequentist framework. MetaInsight, an online platform, supports network meta-analysis by utilizing the Netmeta package in R for frequentist statistical assessments.

Subgroup analysis Not applicable.

Sensitivity analysis No applicable.

Country(ies) involved Taiwan.

Keywords Hepatitis C, direct-acting antiviral, sustained virologic response, ribavirin, meta-analysis.

Contributions of each author

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