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**ADMINISTRATIVE INFORMATION**

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**Review Stage at time of this submission** - Formal screening of search results against eligibility criteria.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202480088

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 August 2024 and was last updated on 19 August 2024.

**INTRODUCTION**

**Review question / Objective** Are there differences in gut flora and uremic toxin levels between patients with chronic kidney disease combined with constipation and non-constipated patients with chronic kidney disease? If probiotic and prebiotic interventions are administered to patients with combined constipation, do the patients' constipation symptoms, uremic toxin levels, and intestinal flora change.

**Condition being studied** Constipation is a common complication in patients with chronic kidney disease (CKD), especially end-stage renal disease (ESRD). Constipation-induced adverse changes in the gut microbiota may lead to the production and accumulation of enterogenous uremic toxins, thereby accelerating CKD

progression. However, currently, there are no accepted clinical guidelines for the diagnosis, pathogenesis, and treatment of CKD-related constipation.

**METHODS**

**Participant or population** We performed a literature search based on the following inclusion criteria: population: patients with chronic kidney disease; intervention and comparator: Stool consistency, frequency, and use of laxatives; outcomes: Determination of disease-associated intestinal flora based on constipation; full-text articles in English. The exclusion criteria were as follows: studies that did not target patients; studies that did not involve exposure to constipation; studies that did not report the outcomes of interest; and duplicate studies.

**Intervention** The review focuses on studies conducted on chronic kidney disease patients with constipation, analyzing the effects of constipation and the degree of constipation, constipation treatment plan on patients' intestinal flora and quality of life.

**Comparator** The review focuses on studies conducted on chronic kidney disease patients with constipation, analyzing the effects of constipation and the degree of constipation, constipation treatment plan on patients' intestinal flora and quality of life.

**Study designs to be included** We will include randomised trials to assess the beneficial effects of the treatments, and will supplement these with observational studies (including cohort and case-control studies) for the assessment of harms.

**Eligibility criteria** We performed a literature search based on the following inclusion criteria: population: patients with chronic kidney disease; intervention and comparator: Stool consistency, frequency, and use of laxatives; outcomes: Determination of disease-associated intestinal flora based on constipation; full-text articles in English. The exclusion criteria were as follows: studies that did not target patients; studies that did not involve exposure to constipation; studies that did not report the outcomes of interest; and duplicate studies.

**Information sources** We searched PubMed, EMBASE and the Cochrane Central Register of Controlled Trials electronic databases for articles describing studies of gut flora describing the effects of constipation on chronic kidney disease. The following keyword combinations were used in the search: The search was performed using the following combinations of keywords: ("constipation" OR "chronic constipation" ) AND ("chronic kidney disease" OR "chronic kidney failure") AND ("gut microbiota" OR "intestine flora") AND ("Incidence" OR "Disease progression" OR "Clinical deterioration"). Synonyms for constipation, gut microbiota, chronic kidney disease, and disease progression were included among Medical Subject Headings (MeSH) terms, EMBASE subject headings, and text words. The search was limited to studies published in the English language. Data for this review were identified by searching PubMed and Embase as well as the Cochrane Library . Only articles published in English up to May 1, 2024 were included.

**Main outcome(s)** We adopted stool characterization, frequency, and the use of laxatives or not to assess the degree of constipation in our patients.

**Quality assessment / Risk of bias analysis** A validated tool was used to evaluate risk of bias based on study design. The Risk of Bias Assessment Tool for Non-randomized Studies (RoBANS) 2.0 was used for nonrandomized studies. This tool comprises eight domains: possibility of target group comparisons, target group selection, confounders, exposure measurement, blinding of assessors, outcome assessment, incomplete outcome data, and selective outcomes. Each domain was classified as low, high, or unclear risk of bias. Quality assessments were conducted by two authors , and disagreements were resolved by discussion with a third author.

**Strategy of data synthesis** The study is qualitative in nature and is primarily summary data, presented in graphical form.

**Subgroup analysis** Not applicable.

**Sensitivity analysis** Not applicable.

**Country(ies) involved** China.

**Keywords** Chronic kidney disease; Constipation; Gut microbiota; Enterogenous uremic toxin; Intestinal motility.

#### **Contributions of each author**

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