

# INPLASY

## The effects of soy protein on chronic kidney disease: a systematic review

INPLASY202430028

doi: 10.37766/inplasy2024.3.0028

Received: 08 March 2024

Published: 08 March 2024

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### ADMINISTRATIVE INFORMATION

**Support** - Not available.

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

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202430028

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 March 2024 and was last updated on 08 March 2024.

### INTRODUCTION

**Review question / Objective** This meta-analysis was conducted to investigate the effects of consuming soy protein with isoflavones in individuals diagnosed with CKD, employing more novel and fuller systematic researches.

**Condition being studied** As previously mentioned, research examining the impact of dietary soy on the management of CKD has yielded inconsistent results, with conflicting systematic findings. Consequently, this meta-analysis was conducted to investigate the effects of consuming soy protein with isoflavones in individuals diagnosed with CKD, employing more novel and fuller systematic researches.

### METHODS

**Participant or population** CKD patients.

**Intervention** Soya protein intake.

**Comparator** Usual Dietary Intakes.

**Study designs to be included** RCT studies which focus on the influence of Soya protein intake on CKD.

**Eligibility criteria** This study aimed to identify randomized, controlled trials employing either a crossover or parallel design, with a minimum follow-up period of 4 weeks, that were specifically designed to assess the impact of soy diets, soy protein, or soy isoflavones on patients diagnosed with chronic kidney disease (including those undergoing dialysis). Inclusion criteria were limited to adult patients aged 18 years and older with renal dysfunction or kidney failure. During the initial screening process, certain exclusion criteria were applied, including participants below the age of 18, studies focusing on pharmacokinetics and basic research, patients who had undergone renal transplantation, as well as reviews and editorials.

**Information sources** Embase Pubmed Cochrane.

**Main outcome(s)** Soya protein intake is good to some CKD patients.

**Quality assessment / Risk of bias analysis** Two of the present authors conducted individual evaluations of the studies to assess compliance with the inclusion criteria subsequent to the primary screening. Subsequently, a pre-tested data extraction form was employed to gather the subsequent information: the identity of the primary author; year of publication; gender and renal function of the participants; classification of chronic kidney disease (diabetic nephropathy or non-diabetic nephropathy); total number of participants; nature of the intervention; protein content of the diet and proportion of soy protein; duration of the follow-up period; design of the study; and quality of the trial. Additionally, baseline data and final concentrations (or net changes) were extracted. The quality of each study was assessed based on several criteria, including allocation concealment, randomization, blindness (participants and outcome assessor), compliance, and withdrawals. A study was considered to have a low risk of bias if it met the criteria of allocation concealment, randomization, and blindness, and if a compliance evaluation had been conducted and the number of withdrawals and reasons had been reported. Conversely, a study that did not meet at least three of these criteria was considered to have a high risk of bias, while other studies were classified as having a moderate risk of bias. As for Yari et al.[15-17] that did not provide the contents of isoflavones, we calculated it based on the concentration of isoflavones in traditional soy products which is about 3.5 mg isoflavones per 1 g soy protein[18].

**Strategy of data synthesis** The meta-analysis was conducted using the Cochrane Collaboration's methodology for review. Weighted median differences or standard median differences were employed to describe the net changes in continuous variables with a formal distribution. The results obtained at the end of each intervention were utilized for analysis. Heterogeneity between studies was assessed using the Q-statistic, while the degree of inconsistency was quantified using I<sup>2</sup>. The level of variability among the trials under consideration was determined by quantifying the proportion of total between-study variance attributable to heterogeneity rather than random variation, as measured by the I<sup>2</sup> statistic using the formula  $I^2 = 100\% \cdot (Q-df)/Q$ [19]. In instances where significant heterogeneity was observed across the trials, results were presented using a random-effects model, while a fixed-effects model was employed in cases where heterogeneity was

not significant[20]. The analyses were conducted using RevMan (Version 5.3, Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration) as the Review Manager. Subgroup analyses were performed to investigate the potential impact of study design (crossover or parallel), trial duration, and type of CKD on outcomes. Sensitivity analyses were additionally carried out to evaluate the influence of trial quality on the overall effect sizes, specifically by excluding trials with a high risk of bias. In cases where significant heterogeneity was observed, sensitivity analyses were also conducted to identify the source of this heterogeneity.

**Subgroup analysis** We used HD, PD, Diabetes and Hypertension to perform subgroup analysis.

**Sensitivity analysis** We used Egger text method.

**Country(ies) involved** China.

**Keywords** CKD, soya intake.

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

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