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Systematic Review and Clinical Trials Search Protocol for Sulforaphane Formulation Development Insights

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ADMINISTRATIVE INFORMATION

Support - University of Huddersfield.

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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 12 August 2025 and was last updated on 12 August 2025.

INTRODUCTION

Review question / Objective This systematic review critically examines a range of formulation strategies aimed at addressing the key challenges associated with sulforaphane, namely its poor stability, low solubility, and limited bioavailability. By evaluating evidence from preclinical studies, clinical trials, and technological innovations, the review seeks to identify approaches that enhance sulforaphane's physicochemical properties, improve its therapeutic efficacy, and facilitate its successful translation from laboratory research to clinical application.

Rationale There is a growing body of evidence indicating that sulforaphane faces significant formulation challenges, such as poor stability, limited bioavailability, and rapid degradation, which collectively hinder its successful clinical translation. These challenges not only affect its therapeutic potential but also limit its commercial and clinical viability. Therefore, it is essential to systematically review the existing literature and clinical trial data to gain a comprehensive understanding of the diverse formulation strategies that have been explored. Such an analysis will help identify the most promising approaches, highlight current gaps, and guide the development of more effective and clinically translatable sulforaphane formulations.

Condition being studied The clinical potential of sulforaphane is constrained by its poor solubility, limited bioavailability, and stability concerns. This systematic review explores formulation and drug delivery approaches designed to overcome these challenges, with a focus on improving its solubility, absorption, and overall therapeutic effectiveness.

METHODS

Search strategy Titles and abstracts were screened independently by two reviewers in accordance with PRISMA guidelines, applying the following inclusion criteria: (a) sulforaphane as the primary compound studied, (b) original research on

formulation development, (c) evaluation of drug entrapment, release, bioavailability, or biological activity, and (d) publication in English. A comprehensive search of PubMed, MEDLINE, Google Scholar, and Scopus from inception to July 2025 used the terms "Sulforaphane" AND ("formulations" OR "pharmaceutical formulations" OR "drug delivery" OR "drug delivery systems" OR "bioavailability" OR "solubility" OR "absorption"). Non-relevant records were excluded, and full-text articles meeting the criteria were retrieved for detailed assessment. Moreover, clinical trials were identified in the NIH Clinical Trials database (https://clinicaltrials.gov/) using the terms "sulforaphane" OR "SFN," covering all records to July 2025. Eligible studies were completed interventional trials with sulforaphane as the primary intervention and publicly available results. Additional searches were conducted in the WHO ICTRP and EU Clinical Trials Register. Duplicates and trials with unclear interventions were excluded. Key data extracted included trial ID, condition, intervention, participant demographics, phase, and location to summarise the therapeutic scope and methodological features of sulforaphane research.

Participant or population Formulation challenges of sulforaphane.

Intervention Formulation development and delivery strategies of sulforaphane.

Comparator Control formulations.

Study designs to be included Experimental in-vitro and in-vivo studies.

Eligibility criteria For scientific published literature: (a) sulforaphane as the primary compound studied, (b) original research on formulation development, (c) evaluation of drug entrapment, release, bioavailability, or biological activity, and (d) publication in English. For clinical trials: Eligible studies were completed interventional trials with sulforaphane as the primary intervention and publicly available results with no limitation was applied for age, sex and location.

Information sources For scientific literature: PubMed, MEDLINE, Google Scholar and Scopus.
For clinical trials: NIH Clinical Trials database, WHO International Clinical Trials Registry Platform and EU Clinical Trials Register.

Main outcome(s) This study aims to evaluate the impact of various formulation strategies on the solubility, stability, and bioavailability of sulforaphane. By systematically comparing different approaches, the research seeks to determine which methods most effectively enhance sulforaphane's physicochemical properties and improve its potential for clinical application.

Data management The data will be organised in Microsoft Excel or Microsoft Word and securely stored on the University of Huddersfield's OneDrive system.

Quality assessment / Risk of bias analysis The risk of bias for all eligible studies was assessed using a previously established framework [1], which evaluates six key domains: research rationale, methodology, characterisation and testing, results, and discussion and conclusions. Each study was independently reviewed by the research team using this framework.

[1] Khizer, Z., Sadia, A., Sharma, R., Farhaj, S., Nirwan, J. S., Kakadia, P. G., ... & Ghori, M. U. (2021). Drug delivery approaches for managing overactive bladder (OAB): a systematic review. Pharmaceuticals, 14(5), 409.

Strategy of data synthesis Data from all eligible studies were extracted using a predefined template capturing details on formulation type, study aim, manufacturing technique, excipients, characterisation tests, and key findings. The extracted information was then compiled into a table using Microsoft Word 2019.

Subgroup analysis The outcomes were categorised by formulation strategy and subsequently analysed narratively.

Sensitivity analysis Absent in the reviewed literature.

Language restriction Studies published in English were selected.

Country(ies) involved United Kingdom.

Keywords Sulforaphane; Drug Delivery; Formulations; Solubility; Absorption; Clinical Trials.

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