

The Role of Curcumin in Modulating Vascular Function and Structure During Menopause

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ADMINISTRATIVE INFORMATION**Support** - Universiti Kebangsaan Malaysia.**Review Stage at time of this submission** - Data analysis.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202430043**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 March 2024 and was last updated on 12 March 2024.**INTRODUCTION**

Review question / Objective This study will provide a comprehensive information on the role of curcumin in modulating vascular function and structure during menopause.

Condition being studied Menopause is a significant phase in a woman's life associated with hormonal changes and an increased risk of cardiovascular diseases. Vascular dysfunction and remodeling during menopause is a common concern as estrogen levels decline. Curcumin, with its anti-inflammatory and antioxidant properties, emerges as a potential therapeutic agent for vascular dysfunction and remodeling. By addressing curcumin's modulatory effects on vascular function and structure, curcumin may serve as a valuable supplement for menopausal women, providing a solution for cardiovascular health.

METHODS

Search strategy A computerized database search will be performed on OVID, Scopus, Web of Science, and PubMed databases with the following set of keywords: Curcumin AND (arterial stiffness OR aortic stiffness OR endothelial function OR vascular function OR blood pressure OR vascular structure OR menopause OR ovariectomy*). Reference of the included studies will also be manually screened for eligible studies. No restrictions on the date of publication will be applied. Only studies published in English will be included. No geographical restriction will be applied.

Participant or population Menopausal women and preclinical models of menopause.

Intervention Studies that used curcumin as an intervention in the experiment group will be included, regardless of route of administration,

formulation, combination, dose and duration of intervention.

Comparator The comparator groups received either no intervention or were treated with relevant conventional drugs.

Study designs to be included Clinical (randomized controlled trial) and preclinical (in vivo, in vitro, ex vivo) studies will be included. Observational studies, editorial, review, abstract/conference proceedings will be excluded.

Eligibility criteria Any clinical and preclinical studies that reported the role of curcumin in modulating vascular function and/or structure during menopause.

Information sources OVID, Scopus, Web of Science, and PubMed databases will be searched with the following set of keywords: Curcumin AND (arterial stiffness OR aortic stiffness OR endothelial function OR vascular function OR blood pressure OR vascular structure OR menopause OR ovariectomy*). Reference of the included studies will also be manually screened for eligible studies.

Main outcome(s) Changes in vasoreactivity, arterial stiffness, systolic blood pressure, mean arterial pressure, diastolic blood pressure, flow-mediated dilation and blood vessel histology.

Additional outcome(s) Levels of nitric oxide or other vasoactive substances, and inflammatory markers.

Data management Two reviewers (A.A.M.A. and A.U.) will independently extract the data from the included studies based on the predefined, standardized form of data collection. Any disagreement will be resolved through discussion with the third reviewer (N.S.). A data spreadsheet will be created using Microsoft Excel to collect relevant information and data. The following data will be extracted: author, publication time, article title, study design, intervention, findings and the outcome measures.

Quality assessment / Risk of bias analysis The risk of bias will be analyzed independently by two reviewers (A.A.M.A. and A.U.). Any disagreement will be resolved through discussion with the third reviewer (N.S.). The risk of bias in randomized clinical trials will be assessed using the Cochrane risk of bias (RoB) tool. Meanwhile, animal studies will be assessed using Systematic Review Center for Laboratory Animal Experimentation (SYRCLE) risk of bias tool. The main components of this item

are as follows: (1) Selection bias: random sequence generation, baseline characteristics, allocation concealment; (2) Detection bias: random housing, blinding, random outcome assessment; (3) Attrition bias: incomplete outcome data; (4) Reporting bias: selective reporting; and (5) Other bias. For in vitro studies, a customized risk of bias tool based on the Joanna Briggs Institute (JBI) checklist for non-randomized experimental studies (2020) will be used. The customized RoB tool comprises three domains as follows: (1) Reporting quality: source of the drug; dosage of the drug used (2) Performance bias: reliable tools and /or reagents used to measure outcome; and (3) Detection bias: standard/appropriate control used; multiple measurement of outcome performed. Every domain will be assessed to determine whether the risk of bias is high, moderate, low, or unclear risk of bias. However, the scores from the corresponding RoB tool will not be applied as a study eligibility criterion.

Strategy of data synthesis The study characteristics and outcome data will be tabulated and described narratively. A meta-analysis will be conducted if the data permits. The risk of bias will be summarized and reported narratively.

Subgroup analysis Where possible, we plan to evaluate the role of curcumin based on different routes of administrations, various combinations of drugs with curcumin and preclinical model used.

Sensitivity analysis A sensitivity analysis will only be conducted if a meta-analysis was performed.

Language restriction English.

Country(ies) involved Malaysia.

Keywords curcumin; endothelial dysfunction; menopause; ovariectomy; vascular function.

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