INPLASY PROTOCOL

To cite: Alshammari. Efficacy of Complementary and Alternative Medicine in Peripheral Arterial Disease: A Systematic Review. Inplasy protocol 202330001. doi: 10.37766/inplasy2023.3.0001

Received: 01 March 2023

Published: 01 March 2023

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Support: **None.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

Efficacy of Complementary and Alternative Medicine in Peripheral Arterial Disease: A Systematic Review

Alshammari, MK[1].

Review question / Objective: **To explore various CAM therapies available and to generate evidence that these therapies are effective for managing the disease.**
Condition being studied: **Peripheral arterial disease (PAD) is described as the atherosclerotic process of arteries other than cerebral and coronary arteries i.e. the abdominal aorta, iliac, and arteries of the lower limb which leads to the narrowing and blocking of arteries.**
Information sources: **An online systematic literature search will be done from the time of database inception from 5 electronic databases namely PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), Ovid SP, ISI Web of Science, Elsevier Science Direct, and Wiley Online Library.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 March 2023 and was last updated on 01 March 2023 (registration number INPLASY202330001).

INTRODUCTION

Review question / Objective: **To explore various CAM therapies available and to generate evidence that these therapies are effective for managing the disease.**

Rationale: **Globally, Complementary, and alternative medicine (CAM) are used for variety of diseases. There is growing evidence that CAM can be used in Peripheral arterial disease (PAD. However, to date there is a scarcity of scientific consensus that sum up the effect of all**

CAM used in observational and experimental studies. Therefore this systematic review will be aiming to review the quality of all the studies that have assessed the effect of CAM in comparison with the modern regimens and also quantify the effect of CAM versus other recommended treatments.

Condition being studied: Peripheral arterial disease (PAD) is described as the atherosclerotic process of arteries other than cerebral and coronary arteries i.e. the abdominal aorta, iliac, and arteries of the lower limb which leads to the narrowing and blocking of arteries.

METHODS

Search strategy: The search terms were "Alternative medicine" OR "Complementary medicine" OR "Dietary supplements" OR "Herbal medicine" OR "Phytotherapy" OR "Homeopathy" OR "Acupuncture" OR "Padma 28" OR "Gingko biloba" OR "Chelation therapy" OR "Medicinal plants" OR "Massage therapy" OR "Exercise Therapy" AND "Peripheral arterial disease" OR "Peripheral arterial occlusive disease" OR "Intermittent Claudication".

Participant or population: Adult Patients suffering from Peripheral Arterial Disease.

Intervention: Any complementary & alternate intervention approved according to guidelines and mentioned in the studies that meet the inclusion criteria of this studyAll complemrary and alternative medicines.

Comparator: Any placebo or comparator eligible for inclusion in this study.

Study designs to be included: Both observational and experimental study designs will be included.

Eligibility criteria: All English language article using cross-sectional, cohort, case control or randomized clinical trial design will be considered for inclusion.

Information sources: An online systematic literature search will be done from the time of database inception from 5 electronic databases namely PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), Ovid SP, ISI Web of Science, Elsevier Science Direct, and Wiley Online Library.

Main outcome(s): Improvement in the following parameter before and after consuming the regimen. Walking Distance/ Time, Quality of Life, Vascular Function, Claudication Distance/Time.

Additional outcome(s): None.

Data management: For this review, all the studies will be broadly classified into categories i.e., . This classification was based on the interventions mentioned in the study. Further sub-group classifications will be done where necessary to create a pool of studies with similar interventions so that the effect could be estimated. The interpretation will be performed using evidence-based medicine guidelines by Cochrane.

Quality assessment / Risk of bias analysis: Cochrane risk of bias tool will be used for the quality assessment. This tool addresses six domains of studies to determine the risk of bias and these domains are Sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other issues. Each of these items in the tool was either labeled "high risk," "low risk" or "unclear risk".

Strategy of data synthesis: Revman 5.4 software will be used for preforming meta-analysis. Random effect model will be used to estimate the effect size.

Subgroup analysis: Subgroup analysis will be performed to identify the causes of heterogeneity and variation of the effect size among the different treatments.

Sensitivity analysis: If the relevant quantitative data is available (i.e continuous data, ordinal data, binary data)

in the studies included subgroup analysis will be performed. To narrow down the level of evidence in the light of the heterogeneity among the group further analysis will be performed using recommended statistical measures so that a solid conclusion can be made on the level of evidence for CAM in PAD.

Language restriction: Only English Language papers will be included in this study.

Country(ies) involved: Saudi Arabia.

Other relevant information: The titles and abstracts of the studies will be screened to determine whether they met the inclusion criteria. In circumstances where further information was required to decide the full text of the article will be read. Any conflict regarding the selection of study was resolved by mutual consensus.
Information extracted from the research articles will be the Author's name, Publication year, Study title, Place of study, Study design, Population characteristics (Sample size & Mean age), Duration of study, Intervention Comparator, and Outcome. The outcomes will be addressed as changes in parameters from baseline until the end of the intervention for both the control/placebo & intervention groups.

Keywords: Peripheral arterial disease, Complementary medicine, Alternative medicine, Systematic review, intermittent claudication.

Dissemination plans: Research article upon completion will be published in peer reviewed journals. In addition, the results will also be presented in scientific conferences locally or internationally.

Contributions of each author:
Author 1 - Mohammed Kanan Alshammari - Conceptualization and Drafting the Manuscript.
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