INPLASY PROTOCOL

To cite: Xu et al. Efficacy and safety of curcumin in diabetic retinopathy: A protocol for systematic review and meta-analysis. Inplasy protocol 202250002. doi: 10.37766/inplasy2022.5.0002

Received: 01 May 2022

Published: 01 May 2022

Corresponding author:
Jiayu Xu

511078909@qq.com

Author Affiliation:
Heilongjiang University of Chinese Medicine

Support: **None.**

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

Conflicts of interest:
None declared.

Efficacy and safety of curcumin in diabetic retinopathy: A protocol for systematic review and meta-analysis

Xu, J[1]; Wang, L[2]; Sun, H[3]; Wang, H[4].

Review question / Objective: **The aim of this meta-analysis is to comprehensively assess curcumin's efficacy and safety in treating DR and provide helpful evidence for the clinical management of the disease.**
Condition being studied: **Diabetic retinopathy is one of the most common complications in diabetic patients. DR has become a major global cause of blindness in the population. Curcumin, an extract of turmeric, has apparent efficacy in diabetes, and studies on curcumin for DR also have been increasing in recent years. However, there is no systematic review of its efficacy in the treatment of DR. This study will conduct a systematic review and meta-analysis of currently published randomized controlled trials of curcumin for the treatment of DR to assess the efficacy and safety of curcumin for the treatment of DR patients.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 May 2022 and was last updated on 13 July 2022 (registration number INPLASY202250002).

INTRODUCTION

Review question / Objective: **The aim of this meta-analysis is to comprehensively assess curcumin's efficacy and safety in treating DR and provide helpful evidence for the clinical management of the disease.**

Condition being studied: **Diabetic retinopathy is one of the most common complications in diabetic patients. DR has become a major global cause of blindness in the population. Curcumin, an extract of turmeric, has apparent efficacy in diabetes, and studies on curcumin for DR also have been increasing in recent years. However, there is no systematic review of its efficacy**

in the treatment of DR. This study will conduct a systematic review and meta-analysis of currently published randomized controlled trials of curcumin for the treatment of DR to assess the efficacy and safety of curcumin for the treatment of DR patients.

METHODS

Search strategy: Number Search terms
1 MeSH descriptor: [Curcumin] explode all trees
2 ((Turmeric yellow*) or (Yellow,Turmeric*) or (Curcumin Phytosome*) or (Phytosome, Curcumin*) or (Diferuloylmethane*) or (Mervia*)): ti, ab, kw
3 Or: 1-2
4 MeSH descriptor: [Diabetic Retinopathy] explode all trees
5 ((Diabetic Retinopathies*) or (Retinopathies, Diabetic*) or (Retinopathy, Diabetic*)): ti, ab, kw
6 Or: 4-5
7 MeSH descriptor: (randomized controlled trial) explode all trees
8 ((clinical study*) or (clinical trial*) or (controlled clinical trial*) or (randomized controlled trial*) or (RCT*) or (random*) or (randomly*) or (trial*)): ti, ab, kw
9 Or: 7-8
10 3 and 6 and 10.

Participant or population: Patients with diabetic retinopathy.

Intervention: The intervention included curcumin, with no limit to dosage form, frequency, and dosage. And intervention could be only Curcumin, Curcumin-phospholipid lecithin formulation, curcumin plus Western medicine and Curcumin plus lifestyle intervention.

Comparator: Control treatment can be any kind of intervention, except curcumin.

Study designs to be included: RCT.

Eligibility criteria: Diagnostic criteria: diabetes history; Microaneurysms, cotton patch, retinal hemorrhage and lipid exudate were observed in the fundus. Risk factors include young-onset diabetes, long course of diabetes, poor blood glucose control, and hypertension.

Information sources: PubMed, Medline, EMBASE, Cochrane Library, China National Knowledge Infrastructure (CNKI), VIP, and Wanfang databases from their respective inception dates to May 2022.

Main outcome(s): The primary outcome is the progression of DR. Secondary outcomes include Visual function (a Logarithmic visual acuity chart was used for recording), fundus signs (including the development of diabetic macular edema, aggravation of hard exudates, Retinal neovascularization), Quality of life and adverse events.

Quality assessment / Risk of bias analysis: The risk of bias of all included RCTs will be assessed by two reviewers via the Cochrane Handbook for Systematic Reviews of Interventions tool, which contains the following 7 items: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and others bias. Each item is classified as “Low risk”, “High risk,” or “Unclear risk”.

Strategy of data synthesis: Data analysis will be conducted by Review Manager5.3 software from the Cochrane collaboration. We will select a random-effect model or fixed-effect model to pool the data according to the results of the heterogeneity test. if I2<50% then the fixed-effect model will be applied for data synthesis. Otherwise, the random-effect model will be conducted if the heterogeneity is significant (I2≥50%). For the dichotomous data, a Mantel-Haenszel (M-H) method will be used to calculate RRs with 95% CI. For continuous data, the inverse variance (IV) method will be used to calculate their mean difference (MD) with 95% CI.

Subgroup analysis: If significant heterogeneity exists and the necessary data are available, subgroup analyses will be performed based on the duration of curcumin treatment, curcumin and concomitant medications, diabetic retinopathy staging, and other types.

Sensitivity analysis: We will use sensitivity analyses to investigate the robustness of main decisions made during the review process to evaluate the stability of our results. The main decision includes sample size, quality of studies, and methodological and missing data.

Country(ies) involved: China.

Keywords: Curcumin, diabetic retinopathy, protocol, systematic review, traditional Chinese medicine.

Contributions of each author:
Author 1 - Jiayu Xu.
Email: 511078909@qq.com
Author 2 - Liyuan Wang.
Author 3 - He Sun.
Author 4 - Hanli Wang.