INPLASY PROTOCOL

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Support: **None.**

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Conflicts of interest:
None declared.

Effectivenes and safety of curcumin in diabetic retinopathy

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Review question / Objective: **The purpose of this study is to analyze the difference between curcumin and curcumin mixture in the treatment of diabetic retinopathy and other treatments except curcumin. The selected studies were randomized controlled trials. We will perform a meta-analysis of data extracted from included RCTS, including DR progression, visual function, fundus signs, quality of life, and adverse events.**
Condition being studied: **Diabetic retinopathy. Personnel: A minimum of three fellows are required. Two reviewers will work independently on the search to identify potentially eligible studies. Discussions were held if disagreements arose. When discussion does not lead to an agreement, a third reviewer will be consulted to resolve the issue. Equipment: The main device used is the computer. The software includes EndNote X9 and Review Manager 5.3 software.**

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 01 May 2022 (registration number INPLASY202250002).

INTRODUCTION

Review question / Objective: **The purpose of this study is to analyze the difference between curcumin and curcumin mixture in the treatment of diabetic retinopathy and other treatments except curcumin. The selected studies were randomized controlled trials. We will perform a meta-analysis of data extracted from included RCTS, including DR progression, visual function, fundus signs, quality of life, and adverse events.**

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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 February 2020.

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.

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