INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest: **None.**

Can dorzolamide/timolol-fixed combination effectively treat primary open-angle glaucoma? A protocol for systematic review and meta-analysis

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Review question / Objective: **Can dorzolamide/timolol-fixed combination (DTFC) effectively treat primary open-angle glaucoma (POAG)?**
Condition being studied: **Primary open-angle glaucoma, dorzolamide, and timolol.**
Information sources: **A comprehensive search will be performed from origin to the March 31, 2020 in the electronic databases of Cochrane Library, MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature, the Allied and Complementary Medicine Database, China National Knowledge Infrastructure, and Wanfang Data. We will not apply limitations related to the language and publication status. We will only consider RCTs that appraised the efficacy and safety of DTFC for the treatment of POAG. We will summarize search strategy sample for Cochrane Library. We will also create similar search strategies for other electronic databases. We will scrutinize other sources, such as Google Scholar, conference proceedings, and reference lists of included trials.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 April 2020 and was last updated on 19 April 2020 (registration number INPLASY202040120.

INTRODUCTION

Review question / Objective: **Can dorzolamide/timolol-fixed combination (DTFC) effectively treat primary open-angle glaucoma (POAG)?**

Condition being studied: **Primary open-angle glaucoma, dorzolamide, and timolol.**

METHODS

Participant or population: **Any patients who were diagnosed as POAG in spite of country, race, gender, age, and severity of POAG will be included.**

Intervention: **In the experimental group, all patients who received DTFC as their solely treatment will be included. There is no limitation on the formulation of DTFC.**

Comparator: **In the control group, subjects could receive any treatments without restrictions. However, we will not consider study which involved any forms of DTFC as its comparator.**

Study designs to be included: Only randomized controlled trials (RCTs) will be included in this study, which explored the efficacy and safety of DTFC for the treatment of POAG.

Eligibility criteria: Only RCTs will be included in this study, which explored the efficacy and safety of DTFC for the treatment of POAG. We will exclude any other studies, such as animal study, review, case report, uncontrolled trial, non-RCTs and quasi-RCTs.

Information sources: A comprehensive search will be performed from origin to the March 31, 2020 in the electronic databases of Cochrane Library, MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature, the Allied and Complementary Medicine Database, China National Knowledge Infrastructure, and Wanfang Data. We will not apply limitations related to the language and publication status. We will only consider RCTs that appraised the efficacy and safety of DTFC for the treatment of POAG. We will summarize search strategy sample for Cochrane Library. We will also create similar search strategies for other electronic databases. We will scrutinize other sources, such as Google Scholar, conference proceedings, and reference lists of included trials.

Main outcome(s): Primary outcomes - Mean intraocular pressure; Best corrected visual acuity. Secondary outcomes - Contrast sensitivity; Bioelectric activity of the retina; Rate of progression of glaucoma; Quality of life (as assessed by 36-Item Short Form Survey); Adverse events.

Data management: Two researchers will independently extract data from all included RCTs using a predefined standard data extraction form. Any divergences between two of them will be resolved through discussion with a third researcher. The extracted information consists of study information (e.g. title, first author), patient characteristics (e.g. diagnosis criteria, eligibility criteria), study methods (e.g. sample size, randomization); details of intervention and controls (e.g. treatment types, dosage), outcome measurements, adverse events, and conflict of interest.

Quality assessment / Risk of bias analysis: Two researchers will independently appraise methodological quality for all eligible RCTs using Cochrane Handbook for Systematic Reviews of Interventions Tool. Any disagreements will be resolved by a third researcher by consultation and a consensus will be reached.

Strategy of data synthesis: RevMan 5.3 software (Cochrane, London, UK) will be utilized to perform statistical analysis. We will estimate continuous outcome values using mean difference or standardized mean difference with 95% confidence intervals (CIs), and dichotomous outcome values using risk ratio with 95% CIs. We will examine heterogeneity using I^2 statistic. We will use a fixed-effect model to pool the data (I^2 ≤50%), and will utilize a random-effect model (I^2 >50%) to synthesize the data. If I^2 ≤50% and sufficient number of eligible study is included, we will carry out meta-analysis. Otherwise, if I^2 >50%, we will conduct a subgroup analysis to investigate the sources of heterogeneity.

Subgroup analysis: A subgroup analysis will be carried out according to the variations in study and patient characteristics, different types of interventions and controls, and different study quality.

Sensibility analysis: A sensitivity analysis will be conducted to test the stability of conclusions by eliminating low quality trials.

Country(ies) involved: China.

Keywords: Primary open-angle glaucoma; dorzolamide; timolol; efficacy; safety