INPLASY PROTOCOL

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

Conflicts of interest: **No.**

Efficacy of transconjunctival approach for the treatment of orbital fractures: a protocol for systematic review and meta-analysis

Qi, YX[1]; Li, SY[2]; Wang, DL[3]; Zhou, PP[4].

Review question / Objective: **Does transconjunctival approach (TCA) effectively treat orbital fractures (OF)?**
Condition being studied: **Orbital fracture; transconjunctival approach.**
Information sources: **Electronic databases sources - We will search the following databases from inception to the March 1, 2020 without limitations of language and publication status: Cochrane Library, MEDLINE, EMBASE, Web of Science, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, China National Knowledge Infrastructure. We will present the search strategy sample of Cochrane Library in table 1, and will also adapt similar search strategies for other electronic databases as well. Other literature sources - In addition, we will also identify grey literature to avoid missing any potential studies, such as dissertations, ongoing trials from clinical trials registries, conference abstracts, and reference lists of associated reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 April 2020 and was last updated on 23 April 2020 (registration number INPLASY202040154).

INTRODUCTION

Review question / Objective: **Does transconjunctival approach (TCA) effectively treat orbital fractures (OF)?**

Condition being studied: **Orbital fracture; transconjunctival approach.**

METHODS

Participant or population: We will include participants who were diagnosed as OF regardless their country, race, sex, and economic sources.

Intervention: In the experimental group, all patients received TCA for treating patients with OF.

Comparator: In the control group, all patients received any interventions for the treatment of eligible patients, except TCA.

Study designs to be included: We will include randomized controlled trials (RCTs) that focus on assessing the efficacy of TCA for the treatment of OF.

Eligibility criteria: We will include randomized controlled trials (RCTs) that focus on assessing the efficacy of TCA for the treatment of OF. However, we will exclude any other studies, such as animal studies, non-clinical trials, non-controlled trials, and non-RCTs.

Information sources: Electronic databases sources - We will search the following databases from inception to the March 1, 2020 without limitations of language and publication status: Cochrane Library, MEDLINE, EMBASE, Web of Science, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, China National Knowledge Infrastructure. We will present the search strategy sample of Cochrane Library in table 1, and will also adapt similar search strategies for other electronic databases as well. Other literature sources - In addition, we will also identify grey literature to avoid missing any potential studies, such as dissertations, ongoing trials from clinical trials registries, conference abstracts, and reference lists of associated reviews.

Main outcome(s): Outcome measures are eyeball protrusion, eye movement, diplopia, sensory disturbance in the inferior orbital innervation area, orbital volume, defect area, fat loss, muscle hernia, and complications.

Data management: We will extract all essential data from included studies following full text screening using data extraction sheet. Two authors will collect data independently, and any different opinions between two authors will be solved by a third author through discussion to reach a consensus decision. The extracted information includes study characteristics (such as title, authors, journal, time of publication, study type, study setting, inclusion and exclusion criteria, et al), patient characteristics (race, age, gender, diagnostic criteria, et al), details of intervention and control, primary and secondary outcomes, safety, and follow-up details.

Quality assessment / Risk of bias analysis: Two authors will evaluate the methodological study quality using Cochrane risk of bias tool. It includes aspects of selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias. Each aspect is further divided into as a low, unclear or high risk of bias. Any unresolved disagreements between two authors will be solved through discussion with another senior author.

Strategy of data synthesis: We will perform statistical analysis using RevMan 5.3 software. All dichotomous data will be expressed as risk ratio and 95% confidence intervals (CIs). All continuous data will be calculated as mean difference or standardized mean difference and 95% CIs. The degree of statistical heterogeneity will be identified using I^2 statistic. Acceptable heterogeneity is considered if $I^2 \leq 50\%$ and a fixed-effect model will be applied. Otherwise, obvious heterogeneity is regarded if $I^2 > 50\%$, and a random-effect model will be utilized. If sufficient clinical and statistical data is collected on the same interventions, comparators, and outcomes, we will conduct meta-analysis when there is homogeneity among included studies. On the other hand, we will perform subgroup analysis or meta-regression to explore the possible reasons for the obvious heterogeneity. In addition, we will also undertake a narrative description to synthesize data.

Subgroup analysis: We will carry out subgroup analysis or meta-regression based on the different interventions, controls and outcome measurements.

Sensibility analysis: To test the robustness of the results data, we will perform sensitivity analysis by excluding studies with high risk of bias.

Country(ies) involved: China.

Keywords: Orbital fracture; transconjunctival approach; efficacy; safety.