International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY

Efficacy and Safety of Cyclosporine A in Preventing Recurrence of Pterygium: A Meta-Analysis

INPLASY202460119
doi: 10.37766/inplasy2024.6.0119
Received: 29 June 2024
Published: 29 June 2024

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ADMINISTRATIVE INFORMATION

Support - This meta-analysis was conducted without any financial support or funding.

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

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202460119

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 June 2024 and was last updated on 29 June 2024.

INTRODUCTION

Review question / Objective To systematically evaluate and synthesize the available evidence on the efficacy and safety of Cyclosporine A in preventing the recurrence of pterygium through a comprehensive meta-analysis of randomized controlled trials and observational studies. This review aims to determine the overall effectiveness of Cyclosporine A as a prophylactic measure against pterygium recurrence and to assess any associated risks or adverse effects.

Condition being studied The pterygium, a common ocular condition characterized by the progressive growth of fibrovascular tissue from the conjunctiva onto the cornea. This condition often leads to visual impairment, discomfort, and aesthetic concerns due to its location and potential to cause corneal distortion and astigmatism. The focus of this meta-analysis is on the recurrence of pterygium following surgical removal, a critical issue in the management of this condition, as repeated surgeries can increase patient morbidity and healthcare costs.

METHODS

Participant or population These patients are patients who have received or are receiving postoperative treatment with cyclocytidine A to reduce the risk of wing recurrence.

Intervention Post-operative use of Cyclosporine A eye drops for pterygium.

Comparator Pterygium surgery without the use of Cyclosporine A eye drops.

Study designs to be included Randomized Controlled Trials (RCTs)、Prospective Cohort Studies、Retrospective Cohort Studies、Controlled Clinical Trials (CCTs).

Eligibility criteria

Inclusion Criteria:
1. Study Design:
- Randomized Controlled Trials (RCTs)
- Controlled Clinical Trials (CCTs)
- Prospective and Retrospective Cohort Studies
2. Participants:
- Patients who have undergone surgical removal of pterygium.
- Studies including any age, gender, or ethnicity.
3. Intervention:
- Use of Cyclosporine A eye drops post-operatively for the prevention of pterygium recurrence.
4. Outcome Measures:
- Recurrence rate of pterygium.
- Adverse events related to Cyclosporine A use.
- Visual acuity and other relevant clinical outcomes.
5. Language:
- Studies published in English.
Exclusion Criteria:
1. Study Design:
- Case Reports and Series.
- Animal Studies.
- Narrative Reviews and Expert Opinions.
2. Participants:
- Studies excluding patients who have undergone surgical removal of pterygium.
3. Intervention:
- Studies evaluating interventions other than Cyclosporine A eye drops.
4. Outcome Measures:
- Studies lacking relevant outcome measures (e.g., no data on recurrence or adverse events).
5. Publication Status:
- Conference abstracts without full-text publication.
- Duplicate publications.
6. Language:
- Studies published in languages other than English, unless a full-text translation is available.

These inclusion and exclusion criteria are designed to ensure that the meta-analysis includes high-quality, relevant studies that directly address the research question regarding the efficacy and safety of Cyclosporine A in preventing pterygium recurrence.

Information sources

1. Electronic Databases:
- PubMed/MEDLINE: For comprehensive coverage of biomedical literature.
- Embase: To capture a broad range of medical and pharmacological studies.
- Cochrane Library: Specifically for systematic reviews and clinical trials.
- Web of Science: For multidisciplinary coverage, including conference proceedings.
- Scopus: For extensive indexing of scientific journals across various disciplines.
2. Grey Literature:
- ClinicalTrials.gov: To identify ongoing and completed trials.
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP): For additional trial registries worldwide.
- Dissertations and Theses Databases: To capture studies not published in peer-reviewed journals.
3. Handsearching:
- Relevant journals in ophthalmology and eye surgery.
- Conference proceedings from major ophthalmology conferences.
4. Reference Lists:
- Review articles, meta-analyses, and systematic reviews on pterygium and Cyclosporine A.
- Textbooks and guidelines in ophthalmology.
5. Contact with Experts:
- Authors of included studies: To request additional data or unpublished studies.
- Professional societies and organizations in ophthalmology.
6. Personal Files:
- Previous reviews or studies conducted by the research team.
- Unpublished data or studies shared within the research community.

Main outcome(s)

1. Recurrence Rate of Pterygium:
- The primary outcome measure, focusing on the incidence of pterygium recurrence following surgical removal and post-operative use of Cyclosporine A eye drops. This will be assessed through the proportion of patients who experience recurrence within a specified follow-up period.
2. Adverse Events Related to Cyclosporine A Use:
- A key secondary outcome, examining the safety profile of Cyclosporine A. This includes but is not limited to:
- Ocular adverse events (e.g., eye irritation, conjunctival hyperemia, increased intraocular pressure).
- Systemic adverse events (if any, though primarily expected to be minimal given the topical application).

Quality assessment / Risk of bias analysis

1. Randomized Controlled Trials (RCTs):
- Use the Cochrane Risk of Bias Tool to assess the following domains:
- Random sequence generation
- Allocation concealment

- Blinding of participants, personnel, and outcome assessors
- Incomplete outcome data handling
- Selective reporting
- Other sources of bias
2. Observational Studies (Cohort, Case-Control):
- Use the Newcastle-Ottawa Scale (NOS) to evaluate the quality of these studies across three main areas:
- Selection of study groups
- Comparability of groups
- Assessment of outcome.

Strategy of data synthesis 1. Data Extraction:
- Use standardized data extraction forms to systematically collect data from each included study.
- Extract information on study characteristics, participant demographics, intervention details, outcome measures, and adverse events.
- Conduct data extraction independently by at least two reviewers to minimize errors and ensure consistency.
2. Assessment of Heterogeneity:
- Calculate the I^2 statistic and Cochran's Q test to assess the degree of heterogeneity among the included studies.
- Consider potential sources of heterogeneity, such as differences in study design, participant characteristics, intervention protocols, and outcome measurement.
3. Meta-Analytic Techniques:
- Use random-effects models to account for heterogeneity and variability between studies.
- For dichotomous outcomes (e.g., recurrence rate), calculate risk ratios (RR) or odds ratios (OR) with 95% confidence intervals (CI).
- For continuous outcomes (e.g., visual acuity), calculate mean differences (MD) or standardized mean differences (SMD) with 95% CI.
4. Publication Bias Assessment:
- Use graphical methods such as funnel plots to visually inspect for publication bias.
- Conduct statistical tests (e.g., Egger's test, Begg's test) to quantify the presence of publication bias.
5. Reporting of Results:
- Summarize the findings using forest plots to visually represent the effect sizes and confidence intervals.
- Provide a narrative synthesis of the results, highlighting key findings and any significant differences between subgroups
6. Software Utilization:
- Use statistical software such as RevMan, Stata, or R for data synthesis and meta-analysis.
- Ensure that all analyses are conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.

Subgroup analysis
Subgroup Analyses:
- Conduct subgroup analyses to explore potential moderators of treatment effects, such as:
- Type of surgery (e.g., conventional vs. advanced techniques).
- Dosage and duration of Cyclosporine A treatment.
- Patient demographics (e.g., age, gender).

Sensitivity analysis
Sensitivity Analysis:
- Perform sensitivity analyses to assess the robustness of the findings, including:
- Exclusion of studies with high risk of bias.
- Inclusion of only high-quality studies.
- Use of fixed-effect models to compare results with random-effects models.

Country(ies) involved China - Anqing Municipal Hospital.

Keywords Pterygium, Cyclosporine A, Recurrence, Ophthalmology, Meta-Analysis.

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