

# INPLASY PROTOCOL

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**Conflicts of interest:**  
None declared.

## Systematic Review and GRADE Evaluation of Traditional Chinese Medicine in the Treatment of Children Meibomian Cyst Based on Randomized Controlled Trials

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**Review question / Objective:** To systematically assess the efficacy and safety of traditional Chinese medicine intervention for meibomian cyst through analysis of randomized controlled trials.

**Information sources:** A comprehensive online search of relevant studies is performed through four main English electronic databases (PubMed, Web of Science, Cochrane Library, Embase), four main Chinese electronic databases (China Biology Medicine (CBM), China National Knowledge Infrastructure (CNKI), WanFang, VIP) and Clinical Trial Registry.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 October 2022 and was last updated on 11 October 2022 (registration number INPLASY2022100039).

**Condition being studied:** Meibomian cyst, also known as a chalazion, is a sterile fatty granuloma that develops when secretions from the eyelid gland are trapped in the lid for some reason. The main clinical symptom is one or more raised lumps under the eyelid or in the lid that slowly increase in size and are not painful. Children are the main group of patients.

### INTRODUCTION

**Review question / Objective:** To systematically assess the efficacy and safety of traditional Chinese medicine intervention for meibomian cyst through analysis of randomized controlled trials.

Currently, surgical excision and curettage is the main Western treatment for children meibomian cyst. However, the risk of recurrence is relatively high, with risks of incomplete removal, bleeding, postoperative lid entropion, and inadvertent injury to the lacrimal duct. The conservative treatment methods in Western medicine are usually hormone injections or anti-inflammatory eye drops dabbed next to the cyst and hot compresses, which are not effective in clinical practice. In contrast, in recent years, many studies have reported that traditional Chinese medicine plays an important role in the treatment of children meibomian cyst, but it lacks certain reliability. Therefore this study is conducted to systematically evaluate the clinical efficacy of traditional Chinese medicine in the treatment of children meibomian cyst and GRADE evaluation to provide a reliable reference for the clinical efficacy of traditional Chinese medicine interventions in the treatment of children meibomian cyst.

## METHODS

**Participant or population:** Children were diagnosed with chalazion cyst, aged 0-12 years, without restricting the gender, or course.

**Intervention:** The experimental group was treated with traditional Chinese medicine and conventional hot compresses.

**Comparator:** The control group was treated with western basic therapies or conventional hot compresses.

**Study designs to be included:** Randomized controlled trial will be included in this study.

**Eligibility criteria:** Inclusion criteria: ① Type of literature: randomized controlled trial in Chinese and English; ② Subjects: children diagnosed with meibomian cyst, aged 0-12 years; ③ Intervention: the experimental group was treated with traditional Chinese medicine and conventional hot compresses, while the control group was

treated with western basic therapies or conventional hot compresses. ④ The sample size in each group was  $\geq 15$ ; ⑤ Outcome indicators: the total efficiency and recurrent rate in both groups. Exclusion criteria: ① duplicates in various databases; ② animal experiments and mechanistic research literature; ③ literature with unreasonable design: non-randomized control or no control group, etc; ④ literature related to meibomian cyst but conference papers, case reports or empirical literature; ⑤ literature that meet the requirements but full text is not available or only abstracts of articles are available; ⑥ studies literature with low credibility of data and inconsistent validated outcome indicators.

**Information sources:** A comprehensive online search of relevant studies is performed through four main English electronic databases (PubMed, Web of Science, Cochrane Library, Embase), four main Chinese electronic databases (China Biology Medicine (CBM), China National Knowledge Infrastructure (CNKI), WanFang, VIP) and Clinical Trial Registry.

**Main outcome(s):** The total efficiency is the main outcome.

**Additional outcome(s):** Recurrent rate is as the additional outcome.

**Data management:** The search date in this study is from published up to October 10th, 2022.

**Quality assessment / Risk of bias analysis:** Our study will use three methods to assess the quality of the literature. First, the Cochrane literature quality evaluation criteria: ① whether the literature design reflects random assignment; ② whether the literature conceals the trial allocation scheme; ③ whether the literature is blinded among the three parties: the children meibomian cyst, the physician who administered the intervention, and the

statistician who evaluated the results; ④ whether the outcome data to be collated are comprehensive and without missing; ⑤ whether the literature has selective reporting bias for positive results; and ⑥ other bias. The risk of bias is also mapped for the included literature with the help of Review Manager 5.3 software. Second, a modified JADAD score is used to re-evaluate the quality of the included literature in accordance with the Chinese medicine intervention for children meibomian cyst, and a rating scale is developed to assess the quality of the included literature in various aspects and to provide a reference for the quality of the literature at different levels for this study. Third, the level of evidence is further evaluated with the help of GRADE evaluation.

**Strategy of data synthesis:** Statistical analysis of the study is performed using STATA 14.1 software, as presented by forest plots. The study expresses the count data of the included literature by ratio (OR) and its 95% confidence interval (CI), setting the statistical value to  $P \leq 0.05$  to tabulate the difference is statistically significant.  $I^2$  is used to quantify the heterogeneity of this included children meibomian cyst literature. When the obtained results  $P > 0.1$  and  $I^2 < 50\%$  suggest that there is no heterogeneity in the literature included in this study, a fixed-effects model can be used for systematic analysis of the outcome efficiency rate; if  $P \leq 0.1$  and  $I^2 \geq 50\%$  indicate heterogeneity in the literature, a random-effects model is used for systematic analysis of the outcome efficiency rate. Statistical analysis of the study is performed using STATA 14.1 software, as presented by forest plots. The study expressed the count data of the included literature by ratio (OR) and its 95% confidence interval (CI), setting the statistical value to  $P \leq 0.05$  to tabulate the difference is statistically significant.  $I^2$  is used to quantify the heterogeneity of this included children meibomian cyst literature. When the obtained results  $P > 0.1$  and  $I^2 < 50\%$  suggest that there is no heterogeneity in the literature included in

this study, a fixed-effects model can be used for systematic analysis of the outcome efficiency rate; if  $P \leq 0.1$  and  $I^2 \geq 50\%$  indicate heterogeneity in the literature, a random-effects model is used for systematic analysis of the outcome efficiency rate.

**Subgroup analysis:** If  $P \leq 0.1$  and  $I^2 \geq 50\%$  indicate heterogeneity in the literature, a random-effects model is used for systematic analysis of the outcome efficiency rate. Further, subgroup analysis is performed according to concrete intervention like traditional Chinese medicine by oral; traditional Chinese medicine by fumigation and traditional Chinese medicine by hot compress.

**Sensitivity analysis:** Sensitivity analysis is performed on the literature included in this study by STATA 14.1 software, and if none of the literature causes significant interference with the results of this analysis, the results of this study are stable.

**Country(ies) involved:** China.

**Keywords:** meibomian cyst; children; traditional Chinese medicine; systematic review; GRADE evaluation.

**Contributions of each author:**

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