

INPLASY PROTOCOL

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Corresponding author:
Huangping Ai

xiaojij@stu.cdutcm.edu.cn

Author Affiliation:
The Hospital of Chengdu
University of TCM.

Support: 81574035, 81973684;
2021MS061.

Review Stage at time of this submission: Formal screening of search results against eligibility criteria.

Conflicts of interest:
None declared.

INTRODUCTION

Review question / Objective: Meta Analysis the clinical effectiveness of Traditional Chinese Medicine combined with Triamcinolone acetonide in the treatment of erosive oral lichen planus.

Efficacy of Traditional Chinese Medicine in Combination with Triamcinolone Acetonide in the Treatment of Erosive Oral Lichen Planus: A Systematic Review and Meta-Analysis

Ai, HP¹; Yan, H²; Li, LF³; Jin, WQ⁴; Li, ChC⁵; Jin, Zh⁶; Zuo, YL⁷.

Review question / Objective: Meta Analysis the clinical effectiveness of Traditional Chinese Medicine combined with Triamcinolone acetonide in the treatment of erosive oral lichen planus.

Information sources: The computer searches the databases of Zhiwang(CNKI), Wanfang, VIP, CBM, Pubmed, EMBASE and Cochrane Library. And a manual search was used to fill in gaps to determine the completeness of relevant research searches. The search period is set from January 2011 to December 2021. The search is carried out by the combination of subject words and free words. The search words include erosive oral lichen planus, EOLP, oral erosion type flat moss, randomized control, traditional Chinese medical science, traditional Chinese medicine, prescription, Triamcinolone acetonide, etc. All references retrieved are reviewed. To ensure that there are no other documents omitted from the above search terms.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 January 2022 and was last updated on 19 January 2022 (registration number INPLASY202210101).

Condition being studied: Oral Lichen Planus (OLP) is a common chronic inflammatory disease of the oral mucosa that affects middle-aged women more than men and is classified by the WHO as a potentially malignant disease of the oral mucosa. OLP can occur in any part of the

oral mucosa and has a variety of clinical manifestations, including reticular, atrophic, vesicular, blistering and plaque forms. Most patients have symptoms such as roughness, woodiness and pain. In severe cases, the mucosa may become eroded and the pain may increase, affecting the quality of life of the patient. Erosional oral lichen plauns (EOLP) is characterised by inflammation, ulceration and erosion of the oral mucosa. However, the disease is recurrent and treatment with western medicine alone can easily lead to relapse and poor results. Recently, more and more clinical studies have shown that the combination of Traditional Chinese Medicine with Triamcinolone acetonide has significant clinical efficacy in the treatment of erosive oral lichen planus, promoting the healing of the erosive surface, improving pain and reducing the recurrence rate. Based on this, this study used the Cochrane systematic evaluation method to conduct a Meta-analysis of the clinical efficacy of Traditional Chinese Medicine combined with Triamcinolone acetonide in the treatment of EOLP, and a fixed-effect model and a random-effect model were determined based on heterogeneity. If heterogeneity exists, sensitivity analysis, subgroup analysis and publication bias can be used to find sources of heterogeneity with a view to providing a higher level of evidence-based medical evidence for clinical treatment.

METHODS

Participant or population: Erosive Oral Lichen Planus.

Intervention: Traditional Chinese Medicine in combination with Triamcinolone acetonide.

Comparator: Simple western medicine routine treatment.

Study designs to be included: The type of study is randomized controlled trials, clinical trials, with or without blind methods.

Eligibility criteria: 1.The type of study is randomized controlled trials, clinical trials, with or without blind methods. 2 Study population Patients diagnosed with EOLP according to clinical presentation or pathology, whose age, gender or race were not restricted. 3 The intervention measures were as follows: the control group was treated with routine western medicine alone, and the experimental group was treated with Chinese herbal medicine or Chinese patent medicine in combination with Triamcinolone acetonide in unlimited doses.4. The outcome indicators included total effective rate, area of oral mucosal lesions, oral pain VAS, healing time, immune factor and inflammatory factor detection, symptom score, recurrence rate,safety observation,quality of life and adverse events.

Information sources: The computer searches the databases of Zhiwang(CNKI), Wanfang, VIP, CBM, Pubmed, EMBASE and Cochrane Library. And a manual search was used to fill in gaps to determine the completeness of relevant research searches. The search period is set from January 2011 to December 2021. The search is carried out by the combination of subject words and free words. The search words include erosive oral lichen planus, EOLP, oral erosion type flat moss, randomized control, traditional Chinese medical science, traditional Chinese medicine, prescription, Triamcinolone acetonide, etc. All references retrieved are reviewed. To ensure that there are no other documents omitted from the above search terms.

Main outcome(s): Total effective rate, area of oral mucosal lesions, oral pain VAS, healing time, immune factor and inflammatory factor detection, symptom score, recurrence rate. The total effective rate, area of oral mucosal lesions, oral pain VAS, healing time, immune factor and inflammatory factor detection, symptom score, recurrence rate were analyzed by RevMan 5.3 software.

Data management: Literature was screened independently by 2 researchers

based on inclusion exclusion criteria and then merged. For controversial literature, the literature that was difficult to identify was assessed either by discussion or by asking a third party. The title and abstract were read first for primary screening, and after excluding literature that clearly did not meet the inclusion criteria. Further reading of the full text of the literature that might meet the inclusion criteria was re-screened. The following elements were extracted from each article: the surname of first author, year of publication, type of study, search site, sample size, mean age and age range, intervention, outcome, and judgment of irrelevant variables. These data were extracted independently by two researchers, and any disagreement between them was discussed and evaluated by a third party and finally agreed upon.

Quality assessment / Risk of bias analysis:

Four researchers independently assessed the risk of bias in the study. The bias risk assessment tool of Cochrane system evaluator manual was used to assess the bias risk of the included RCT, including the generation of random sequences, allocation hiding, blind evaluation of subjects and researchers, blind evaluation of research outcomes, integrity of data, selective reporting of research results and other sources. According to the above seven aspects, three assessment choices of high risk, uncertainty and low risk were made.

Strategy of data synthesis: Using the RevMan 5.3 software provided by the Cochrane Collaboration. Risk ratio (RR) was used for counts. Mean Difference (MD) was used for continuous variables, both expressed as effect values with 95% confidence interval (CI). Subgroup analysis or one-study removal was performed according to possible heterogeneity factors between studies. Statistical heterogeneity was assessed by the P, I² test: if P>0.1, I²≤50%, homogeneity was considered good, and the fixed effect model; if P≤0.05, and statistical heterogeneity is large, random effect model is used, and a

sensitivity analyses or subgroup analyses, and funnel plots were used to analyze the presence of publication bias for those analyzing ≥10 documents.

Subgroup analysis: If there is statistical heterogeneity among the results ($p < 0.1, I^2 > 50\%$), the random effect model is used to estimate the combined effect. If there is statistical heterogeneity, a subgroup analysis is conducted to explore the source of the heterogeneity, including different outcome indicators.

Sensitivity analysis: After deleting any study, a new meta analysis was conducted to see if the effect changed. If the result after deletion is different from that of the previous merger, it is considered that this study has a great impact on the total effect, otherwise, it is small. When looking at the sources of heterogeneity, if a study is deleted, the heterogeneity is significantly reduced, then this study is considered to be the main source of heterogeneity.

Country(ies) involved: China.

Keywords: Erosive Oral Lichen Planus; Traditional Chinese Medicine; Triamcinolone Acetonide; effective rate; Systematic review; Meta-analysis.

Contributions of each author:

Author 1 - Huangping Ai.

Author 2 - Hang Yan.

Author 3 - Lingfeng Li.

Author 4 - Wenqing Jin.

Author 5 - Chuncai Li.

Author 6 - Zhao Jin.

Author 7 - Yuling Zuo.