INPLASY PROTOCOL

To cite: Xie et al. Vitamins for aphthous stomatitis : a systematic review and meta-analysis. Inplasy protocol 2020100034. doi: 10.37766/inplasy2020.10.0034

Received: 10 October 2020

Published: 10 October 2020

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Support: **No. 2018WS163; No. 2019WS045.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None.

Vitamins for aphthous stomatitis : a systematic review and meta-analysis

Xie, Z[1]; Sun, L[2]; Dao, F[3]; Lu, R[4]; Shi, J[5]; Zong, M[6]; Qin, J[7].

Review question / Objective: **This study is intending to evaluate the effectiveness and safety of vitamins for aphthous stomatitis.**
Condition being studied: **Aphthous stomatitis, also called canker sore, is a self-limiting superficial disease that occurs on the patient's oral mucosa. It is one of the widespread oral mucosal lesions in clinical care. Although aphthous stomatitis are self-limiting, the severe pain caused by ulcers can negatively affect the mood, pronunciation, and diet of patients.There are many ways to treat aphthous stomatitis, but many of the treatments are not effective. In the general population, the incidence of aphthous stomatitis is as high as 25%, and the recurrence rate within three months is as high as 50%. Systemic diseases, the lack of nutrition, genetic, etc may be the main cause of aphthous stomatitis. The etiology of aphthous stomatitis is still unknown, making it difficult to diagnose based on medical history and clinical criteria.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 October 2020 and was last updated on 10 October 2020 (registration number INPLASY2020100034).

INTRODUCTION

Review question / Objective: **This study is intending to evaluate the effectiveness and safety of vitamins for aphthous stomatitis.**

Rationale: **Some studies have proved that vitamin supplementation for patients can have a better effect on the treatment of patients with aphthous stomatitis.**

Condition being studied: **Aphthous stomatitis, also called canker sore, is a**

self-limiting superficial disease that occurs on the patient's oral mucosa. It is one of the widespread oral mucosal lesions in clinical care. Although aphthous stomatitis are self-limiting, the severe pain caused by ulcers can negatively affect the mood, pronunciation, and diet of patients.There are many ways to treat aphthous stomatitis, but many of the treatments are not effective. In the general population, the incidence of aphthous stomatitis is as high as 25%, and the recurrence rate within three months is as high as 50%. Systemic diseases, the lack of nutrition, genetic, etc may be the main cause of aphthous stomatitis. The etiology of aphthous stomatitis is still unknown, making it difficult to diagnose based on medical history and clinical criteria.

METHODS

Participant or population: Patients who diagnosed (first diagnose) with aphthous stomatitis according to clear diagnostic criteria, regardless of gender, age.

Intervention: Vitamins, as a kind of essential organic compounds, are also widely used in primary care. Studies have shown that the supplementation of vitamin B and vitamin C is beneficial to reduce the degree of pain , the recurrence of oral ulcers, the number and size of ulcers and the time of healing.

Comparator: No treatment, placebo, and any other type of active intervention will be included in control groups.

Study designs to be included: All randomized controlled trials(blinded or not), regardless of language or publication date or state, will be screened.

Eligibility criteria: (1)Population: patients who diagnosed (first diagnose) with aphthous stomatitis according to clear diagnostic criteria, regardless of gender, age; (2)Intervention：Vitamins (not limited to specific types); (3)Control:As long as vitamins are not included, no treatment, placebo, and any other type of active intervention will be included in control groups.

Information sources: PubMed, the Cochrane Library, EMBASE, Chinese National Knowledge Infrastructure Database (CNKI), VIP Chinese Science and Technique Journals Database, Wanfang Database, grey literature, clinicaltrials.gov, and Chinese clinical trial registry will be searched from the studies published to September 2020. was also searched.The reference lists of all studies identified by the above methods will be checked.

Main outcome(s): The duration of symptom; (2) Cure rates.

Additional outcome(s): (1)The time of treatment;(2)The rate of recurrence; (3) Satisfaction with treatment; (4)The degree of pain; (5) Adverse events; (6)Adverse Drug Reaction.

Data management: NoteExpress will be used to manage all the articles retrieved. Duplicated records will be excluded first. Two independent authors(ZW Xie and L Sun) will screen the abstract/title and full text separately. Data extraction will be performed by two researchers based on standardized data extraction tables. Two authors(ZW Xie and L Sun) independently and repeatedly extracted the data and cross-checked the data. Discrepancies can be resolved by discussion(ZW Xie and L Sun) with the researcher or arbitration by the senior author (Z Min).

Quality assessment / Risk of bias analysis: The modification of the Cochrane Risk of Bias tool will be used to assess the risk of bias. The following criteria are included in the modification of the Cochrane Risk of Bias tool: random sequence generation (selection bias); allocation concealment (selection bias); blinding (performance bias and detection bias); incomplete outcome data (attrition bias); selective report (reporting bias); other bias. Publication bias will be used by funnel plot(≥10 trials).

Strategy of data synthesis: RevMan 5 will be used to process the results. The mean

difference(MD) will be used to calculate the continuous outcomes. Relative risk(RR, Mantel-Haenszel, RR) will be used to assess the dichotomous variable. We will also calculate the P-value and 95% confidence interval (95%CI).

Subgroup analysis: I2 will be used to calculated the heterogeneity. The fixed-effect model will be used to synthesize data with insignificant heterogeneity (I2<50%). The random-effects model will be used to synthesize data with significant heterogeneity(I2≥50%). Potential sources of heterogeneity may be analyzed: the passway of treatment; age; the type of vitamins combined; the dosage of vitamins; time of treatment.

Sensibility analysis: Sensitivity analysis will be used. The poor methodological quality for sensitivity analysis will be excluded.

Language: English.

Country(ies) involved: China.

Keywords: Vitamins; Aphthous stomatitis; Duration of symptom; Rate of recurrence.

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