INPLASY PROTOCOL

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Conflicts of interest:
None declared.

A protocol for systematic review and bayesian network meta-analysis of Integrated traditional Chinese and Western medicine therapies for Hashimoto Thyroiditis

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Review question / Objective: **To compare and rank several Integrated traditional Chinese and Western medicine therapies in the treatment of Hashimoto Thyroiditis to better inform clinical practice.**
Condition being studied: **Hashimoto Thyroiditis is an organ-specific autoimmune disease, a thyroopenum antibody and a thyroid peroxidase antibody are its iconic antibody. Clinically, the destruction of the filaration structure is characterized by the deterioration of thyroid, cell infiltration, thyroid specific T lymphocytes, and thyroid autogen specifically T lymphocytes. Western medicine treatment is mainly based on immunotherapy and hormone replacement therapy, traditional Chinese medicine has a unique advantage of its treatment.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 March 2022 and was last updated on 20 March 2022 (registration number INPLASY202230106).

INTRODUCTION

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METHODS

Participant or population: The diagnostic criteria of bridge-based monobotitis, regardless of whether the diagnostic criteria refer to the same standard. Such as Fisher.s Diagnostic Standards, Senfa (Japan Hoheng Provincial) Standard, "Chinese Thyroid Disease Diagnosis and Treatment Guide - Thyroxy" in Chinese Medical Association - Diagnostitis in Chronic lymphocytic thyroiditis, People's Health Publishing House Internal Science "Related Diagnostic Standards (7th Edition), Diagnostic Standards (Liu Xinmin Edition)," Laboratory of Chinese Thyroid Diseases - Laboratory of Thyroid Diseases and Auxiliary Examination.

Intervention: The patients in the treatment groups will be given integrated traditional Chinese and Western medicine therapies, such as glucocorticoid, NSAIDs, traditional Chinese Medicine and any combination between them. The trial investigating on the unreleased drug or drug which cannot be covered by the loop would be excluded.

Comparator: Patients in the control group will be given placebo or observation alone or adjuvant treatment.

Study designs to be included: Regardless of the length of treatment, all relevant RCTs using Integrated traditional Chinese and Western medicine therapies for Hashimoto Thyroiditis will be included. NonRCT, quasi-RCTs, cluster RCTs, animal studies, literature reviews will not be involved.

Eligibility criteria: 1. Types of study. Regardless of the length of treatment, all relevant RCTs using Integrated traditional Chinese and Western medicine therapies for Hashimoto Thyroiditis will be included. NonRCT, quasi-RCTs, cluster RCTs, animal studies, literature reviews will not be involved. 2. Participants. Participants (over 18years old) with HT diagnosed with specific criteria (i.e. mention any one of criteria for diagnosis of HT) are eligible for inclusion and there is no restriction on gender, age, severity, et al. However, patients with other diseases, such as autoimmune diseases, pregnancy and thyroid surgery history (including 131 I-therapy) will be excluded.3. Interventions. The patients in the treatment groups will be given integrated traditional Chinese and Western medicine therapies, such as thyroxine, glucocorticoid, traditional chinese medicine, immunosuppressant and any combination between them. The trial investigating on the unreleased drug or drug which cannot be covered by the loop would be excluded. Patients in the control group will be given placebo or observation alone or adjuvant treatment. Figure 1 shows the network of all possible pairwise comparisons among the eligible interventions.4. Outcome measures. The primary outcomes of our concern include total effective rate, score for signs and symptoms, and thyroid clinical indicators including free triiodine-thyroxine (FT3), free thyroxine (FT4), thyroglobulin antibody (TGAb), thyroid stimulating hormone (TSH), thyroid peroxidase antibody (TPOAb). The secondary outcomes are TCM syndrome score, TCM syndromes (total effective rate of TCM syndromes) and adverse event incidence rates.

Information sources: The search strategy for each database had been customized under the guidance of experienced librarians. We will search seven databases, including three English databases and five Chinese databases, from their establishment to May 1, 2021. These databases are PubMed, MEDLINE, EMBASE, The Cochrane Library, China National Knowledge Infrastructure, Wanfang, Chinese Technology Journal Full-text Database and China biomedical literature database. We will use a variety of combinations of Medical Subject Headings and free words for retrieval based on the PICOS strategy (participants, interventions, comparison and studies). In addition, the references of the initially included literature

will be traced back to achieve a comprehensive search. And we will also search clinical registration websites, including WHO International Clinical Trials Registry Platform (apps.who.int/trialsearch/), ClinicalTrials.gov (www.clinicaltrials.gov/) and Chinese Clinical Trial Registry(www.chictr.org.cn/) for the ongoing trials on these sites.

Main outcome(s): The primary outcomes of our concern include total effective rate, score for signs and symptoms, and thyroid clinical indicators including free triiodine-thyroxine (FT3), free thyroxine (FT4), thyroglobulin antibody (TGAb), thyroid stimulating hormone (TSH), thyroid peroxidase antibody (TPOAb).

Additional outcome(s): The secondary outcomes are TCM syndrome score, TCM syndromes (total effective rate of TCM syndromes) and adverse event incidence rates.

Quality assessment / Risk of bias analysis: The Cochrane Collaboration's risk of bias tool will be used to assess the risk of bias in the eligible studies by 2 researchers (Chanyuan Zhou and Changda Li). The evaluation criteria are divided into six entries, each entry uses low, high or unclear risk of bias to judge and divide the research quality. This work will be performed by two researchers independently. The risk of bias in included studies will be shown in the form of graph.

Strategy of data synthesis: Two levels of analyses will be conducted: first, we will perform conventional pair-wise meta-analysis using the Stata13.0. Second, bayesian network meta-analysis will be performed using Stata13.0 software and Winbugs14 software.

Subgroup analysis: If the necessary data are available, subgroup analyses will be done.

Sensitivity analysis: This study does not involve sensitivity analysis.

Country(ies) involved: China.

Keywords: Hashimoto Thyroiditis, Buzhong Yiqi Therapy, protocol, systematic review.

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