INPLASY PROTOCOL

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Corresponding author:
Leixiao Zhang

15156991@qq.com

Author Affiliation:
Department of Integrated Traditional and Western Medicine, West China Hospital, Sichuan University, Chengdu, Sichuan Province, China.

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None declared.

Efficacy and safety of acupuncture for gastrointestinal urticaria: a protocol for systematic review and meta-analysis

Zhang, L[1]; Lu, L[2]; Deng, Y[3]; Cao, W[4]; Liu, Y[5]; Hu, C[6]; Wen, Q[7]; Yao, J[8]; Zhao, Y[9]; Zhao, Y[10]; Lv, J[11]; Zheng, Q[12]; Li, N[13].

Review question / Objective: **To systematically evaluate the effectiveness and safety of acupuncture in the treatment of GU.**

Condition being studied: **Acupuncture is to balance the body's Qi and blood by stimulating acupuncture points and achieve the comprehensive adjustment of the body. The clinical efficacy of acupuncture in the treatment of CU has also been confirmed by some mechanism studies. Acupuncture can regulate body fluids and cellular immunity, enhance the phagocytic ability of macrophages and B cells; correct the balance of Th1 and Th2 lymphocytes; reduce mast cell degranulation and reduce vascular permeability. In addition, acupuncture treatment can also activate endogenous morphine-like substances, inhibit and block the transmission of pain and itching signals, so as to achieve the purpose of analgesia and itching; maintain intestinal flora and immune homeostasis, and promote The release of beneficial bacteria reduces the content of pathogenic bacteria and enhances the stability of the flora itself, thereby having a benign protective effect on maintaining the diversity and abundance of the intestinal flora, achieving the purpose of treating gastrointestinal symptoms.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 July 2021 and was last updated on 26 July 2021 (registration number INPLASY202170086).

INTRODUCTION

Review question / Objective: **To systematically evaluate the effectiveness and safety of acupuncture in the treatment of GU.**

Rationale: **At present, there are many randomized controlled trials (RCTs) on acupuncture in the treatment of CU, with various methods. However, so far, there is no systematic review of the research on the treatment of GU with acupuncture, and the**

best evidence-based evidence is lacking. Therefore, it is necessary to review it and provide clinicians with evidence-based and safe treatment methods.

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METHODS

Participant or population: XRegardless of gender, age, race, education and economic status, CU patients with gastrointestinal symptoms who meet the following diagnostic criteria (eg, EAACI/GA2LEN/EDF/WAO guidelines, guidelines for the diagnosis and treatment of CU).

Intervention: Acupuncture refers to a method of stimulating acupuncture points, including hand needles, leather needles, plum blossom needles, ear needles, electroacupuncture, fire needles or acupoint catgut, etc. Other methods such as acupressure, moxibustion, laser acupuncture, drug acupuncture, dry needle or transcutaneous electrical nerve stimulation will be excluded. Sham acupuncture includes acupuncture at inappropriate acupoints, sham acupuncture at acupoints, sham acupuncture at non-acupoints, non-piercing acupuncture and sham intervention).

Comparator: 1. Acupuncture compared with no treatment. 2. Acupuncture compared with placebo or sham acupuncture. 3. Acupuncture compared with other active therapies. 4. Acupuncture in addition to active therapy compared with the same active therapy. We will evaluate the acupuncturist's education and training, clinical experience, the total number of acupunctures, treatment time, and frequency of treatment.

Study designs to be included: We will include in the RCTs without the limitations of language and publicity. However, animal mechanism studies, case reports, self-controlled, non-randomized controlled trials, random crossover studies, and quasi-randomized trials will be excluded.

Eligibility criteria: We will include in the RCTs without the limitations of language and publicity. However, animal mechanism studies, case reports, self-controlled, non-randomized controlled trials, random crossover studies, and quasi-randomized trials will be excluded.

Information sources: Our systematic review will electronically and manually search for all RCTs for acupuncture treatment of GU, regardless of publication status and language, by December 2021. Databases include: PubMed, EMBASE, Springer, Web of Science, Cochrane Library, WHO International Clinical Trials Registry Platform (ICTRP), Traditional Chinese Medicine databases (TCMD), China National Knowledge Infrastructure (CNKI), China Biomedical Literature Database (CBM), Chinese Scientific Journal Database (VIP) and Wan-Fang database. The following search terms will be used: chronic urticaria, hives, Nettle-Rash, Fong-Tzen-Kwai, Wind-Rash-Patch, Feng Yin Zheng, gastrointestinal, diarrhea, weight loss, abdominal bloating, abdominal pain,

anorexia, acupuncture, manual acupuncture, filiform steel needle, electroacupuncture, fire needling, auricular acupuncture, ear acupuncture, dermal needle, abdominal acupuncture, pyonex, plum blossom needle and acupoint catgut. Use the same search term in the Chinese database. A search strategy will be developed based on the Cochrane Handbook guidelines.

Main outcome(s): The primary outcome used in this analysis was the total effective rate (Effective rate (%) = [(number of patients clinically cured + markedly effective + effective)/number of patients] × 100%. (1) Clinically cured: The skin lesions have subsided, the pruritus has completely disappeared, and scores have decreased by 90% or more after treatment; (2) Markedly effective: The skin lesions have significantly resolved, the pruritus has been significantly alleviated and scores have decreased by 60%–89%; (3) Effective: Skin lesions have resolved, the pruritus has been alleviated and scores have decreased by 20%–59%; 4) Invalid: Skin lesions and pruritus were not significantly resolved, and scores have decreased by less than 20%).

Additional outcome(s): The secondary outcomes included a visual analog scale (VAS) for abdominal pain, urticaria activity score7 (UAS7), Dermatology Life Quality Index (DLQI), recurrence rate and occurrence of adverse events.

Quality assessment / Risk of bias analysis: The authors (YD and WC) will use the Cochrane collaboration's bias risk assessment tool to assess the risk of bias for all included studies. We will assess the risk of deviation in sequence generation, allocation sequence hiding, the blindness of participants and staff, result evaluators, incomplete result data, selective result reporting, and other sources of deviation. This review USES L, U, and H as key to these assessments, where L (low) indicates a lower risk of bias, U (unclear) indicates an uncertain risk of bias and H (high) indicates a higher risk of bias. If inconsistent results occur, the final decision will be made by the third author (NL). The information contained in the study on the biased assessment of risk was summarized in tabular form and the results and impacts were critically discussed. If the information is not clear, we will try to contact the author. For duplicate articles, we select only the original.

Strategy of data synthesis: When the meta-analysis is performed, RevMan V.5.3 will be used for data synthesis. The result will be expressed as the RR value of the binary data and the SMD value of the continuous data. If the I2 test is less than 50%, a fixed effect model is used for data synthesis. If the I2 test is between 50% and 75%, a random effects model is used for data synthesis. If the I2 test is higher than 75%, we will investigate the possible causes from a clinical and methodological perspective and provide a descriptive analysis or a subgroup analysis.

Subgroup analysis: Subgroup analyses will be performed based on the heterogeneity of the acupuncture type (including manual acupuncture, dermal needle, plum blossom needle, ear acupuncture, electro-acupuncture, fire needle or acupoint catgut) and clinical differences.

Sensitivity analysis: To test the robustness of the review conclusions, a sensitivity analysis will be performed for the primary outcome according to the following criteria: sample size, heterogeneity quality and statistical model (random-effects or fixed-effects model). The results will be compared and discussed.

Country(ies) involved: China.

Keywords: acupuncture, gastrointestinal urticaria, systematic review protocol.

Contributions of each author:

Author 1 - Leixiao Zhang.
Email: 15156991@qq.com
Author 2 - Lingyun Lu.
Email: lingyun.lu@scu.edu.cn
Author 3 - Yanli Deng.
Email: 330589174@qq.com

Author 4 - Wei Cao.
Email: 78202747@qq.com
Author 5 - Ying Liu.
Email: 772628889@qq.com
Author 6 - Cheng Hu.
Email: 278453512@qq.com
Author 7 - Qian Wen.
Email: xuwen_7712@qq.com
Author 8 - Junpeng Yao.
Email: yaojunpeng@stu.cdutcm.edu.cn
Author 9 - Ying Zhao.
Email: zhaoying@stu.cdutcm.edu.cn
Author 10 - Yu Zhao.
Email: 10875153@qq.com
Author 11 - Jianqin Lv.
Email: 372651647@qq.com
Author 12 - Qianhua Zheng.
Email: zhengqianhua@cdutcm.edu.cn
Author 13 - Ning Li.
Email: zhenjiuhuaxi@163.com