

INPLASY PROTOCOL

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None declared.

Efficacy and safety of acupuncture in immune regulation on HBV-infected patients. A protocol of systematic review and meta analysis

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Review question / Objective: People with hepatitis B are prone to recurrent infections and need to take medication for a long time. People with hepatitis B are more likely than others to develop cirrhosis and liver cancer. Currently, commonly used treatment options usually increase the ability to eliminate the virus by boosting the immune response, but the available antiviral drugs do not completely eliminate the virus. In recent years, acupuncture has attracted attention for its modulating effects on immune function in hepatitis B patients. The purpose of this systematic review is to accurately evaluate whether acupuncture has a modulating effect on the immune function of hepatitis B patients. **P:** Patients with hepatitis B. **I:** Acupuncture treatment or acupuncture combined with other therapies. **C:** Use of drugs or other therapies in addition to acupuncture. **O:** Efficiency, HBsAg, HBeAg, HBV DNA, pgRNA, inflammation index, T lymphocyte subpopulation, liver function index. **S:** RCT (Randomized Controlled Trial).

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 February 2022 and was last updated on 15 February 2022 (registration number INPLASY202220056).

INTRODUCTION

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the virus. In recent years, acupuncture has attracted attention for its modulating effects on immune function in hepatitis B patients. The purpose of this systematic review is to accurately evaluate whether acupuncture has a modulating effect on the immune function of hepatitis B patients. P: Patients with hepatitis B. I: Acupuncture treatment or acupuncture combined with other therapies. C: Use of drugs or other therapies in addition to acupuncture. O: Efficiency, HBsAg, HBeAg, HBV DNA, pgRNA, inflammation index, T lymphocyte subpopulation, liver function index. S: RCT (Randomized Controlled Trial).

Condition being studied: Hepatitis B is a worldwide health challenge, especially in the Asian region. Long-term hepatitis B infection can cause liver damage, which can eventually lead to cirrhosis and liver cancer. Antiviral medication is the common treatment option for hepatitis B, but it is not indicated for some patients due to their physical condition and other factors. Acupuncture is a part of traditional Chinese medicine and is widely used in clinical practice. Acupuncture has the ability to regulate the body's immune system, relieve pain, and relieve fatigue. In recent years, the role of acupuncture has received more and more attention. The purpose of this study was to evaluate the effectiveness and safety of acupuncture on immune regulation in patients with hepatitis B.

METHODS

Participant or population: Patients who have been clinically diagnosed with hbv, without immune-related diseases.

Intervention: Acupuncture treatment (classic acupuncture, electro-acupuncture and warm Acupuncture) or acupuncture combined with other therapies (For example: traditional Chinese medicine, herbal extracts, drug therapy, etc).

Comparator: Take drugs and other treatment measures, except acupuncture.

Study designs to be included: All randomized Controlled Trials(RCTs) will be included.

Eligibility criteria: Inclusion criteria: 1. Participants were clinically diagnosed hepatitis B patients, age over 18 years old. 2. The study type was a randomized controlled study. Exclusion criteria: 1. Participants with other diseases. 2. Immune-related drug use prior to the intervention in last 6 months.

Information sources: We will search for randomized controlled studies in the following databases: PubMed, Embase, The Cochrane Library, Web of science, China National Knowledge Infrastructure (CNKI), Wanfang, China Science and Technology Journal Database (VIP), Chinese BioMedical Literature Database (CBM). Search the above databases from the establishment of the database to February 2022, without region or language restrictions.

Main outcome(s): After a period of treatment, the effectiveness and safety of acupuncture in regulating immune function in HBV-infected patients were assessed mainly by the following indicators: Efficient rate, HBsAg, HBeAg, HBV DNA, and pgRNA.

Additional outcome(s): Inflammatory indexes (TNF- α , IL-6, IL-1 β), T lymphocyte subsets (CD4+, CD3+, CD4+/CD8+), liver function indexes (ALT, AST, TBil), HBsAg, HBeAg, HBV DNA, pgRNA were used as secondary evaluation indexes.

Quality assessment / Risk of bias analysis: Risk of study bias was assessed using the cochrane risk of bias assessment tool and Revman. Six aspects were assessed according to: random assignment method, assignment scheme, blinding, data integrity, selective reporting of study results, and other sources of bias. The included literature was classified into three levels according to the assessment criteria: bottom risk, high risk, and unclear.

Strategy of data synthesis: Heterogeneity of the study results was tested with I^2 . If $P < 0.1$ and $I^2 \geq 50\%$, it indicates significant heterogeneity of study results, and the random-effects model was selected to merge the data. If $P \geq 0.1$ and $I^2 < 50\%$, the heterogeneity was not significant, and the fixed-effects model was selected to merge the data. The dichotomous data effect size was expressed as the relative risk (RR) with 95% confidence interval (CI). Continuous variables data effect sizes were expressed as mean difference (MD) or Standardized mean difference (SMD) with 95% confidence interval (CI).

Subgroup analysis: If there was significant heterogeneity in the study results, subgroup delineation was performed. Subgroup delineation will be based on age, duration of disease, duration of treatment, type of acupuncture, and acupuncture versus other treatment options.

Sensitivity analysis: Sensitivity analysis was performed on the study results to ensure the stability of the study findings. The sensitivity analysis was considered to be passed if any of the included papers were excluded and the remaining data were combined, and the study findings were not affected.

Country(ies) involved: China.

Keywords: Acupuncture, HBV, Systematic review.

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