INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None declared.

Effect of SLBZS on immunity to diarrhoeal disease - A Systematic Review and Meta-Analysis

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Review question / Objective: **To evaluate preclinical data on Shenling Baizhu powder for the treatment of diarrhoea from an immunological perspective.**
Condition being studied: **Diarrhoea is one of the leading causes of death worldwide and is associated with immune dysfunction. The modulatory effects of Shenling Baizhu powder on immune function in diarrhoeal disease have been validated in various animal models. However, the results of these studies have not been systematically evaluated.**
Information sources: **Seven databases were searched, including PubMed, Embase, Cochrane Library, CNKI, Wanfang Database, VIP and Chinese Medicine Database.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 April 2022 and was last updated on 21 April 2022 (registration number INPLASY202240132).

INTRODUCTION

Review question / Objective: **To evaluate preclinical data on Shenling Baizhu powder for the treatment of diarrhoea from an immunological perspective.**

Condition being studied: **Diarrhoea is one of the leading causes of death worldwide and is associated with immune dysfunction. The modulatory effects of Shenling Baizhu powder on immune function in diarrhoeal disease have been validated in various animal models. However, the results of these studies have not been systematically evaluated.**

METHODS

Participant or population: **Rodent animal models of diarrhoea, with no restrictions on genus or animal modelling methods.**

Intervention: **The experimental group was treated with Shenling Baizhu powderSLBZS**

(unlimited dosage, dose, frequency and duration of treatment).

Comparator: The control group was treated with saline or distilled water intervention.

Study designs to be included: Randomised controlled animal trial.

Eligibility criteria: 1.Rodent animal models of diarrhoea, with no restrictions on genus or animal modelling methods. 2.InterventionsThe experimental group was treated with SLBZS (unlimited dosage, dose, frequency and duration of treatment) and the control group was treated with saline or distilled water intervention.2.Outcome indicatorsOverall condition: body weight, diarrhoea scoreImmune organ level: spleen weight, thymus weightImmune cell level: macrophage phagocytosis, Red blood cells immune complex ring rate (RBC-IC-RR), Red blood cells C3b receptor ring rate (RBC-C3b-RR), the Immunocytokine level: immunoglobulin A (SIgA), pro-inflammatory factors (tumour necrosis factor-α (TNF-α), interleukin-1β (IL-1β), interleukin-8 (IL-8), interleukin-6 (IL-6)); anti-inflammatory factors (interleukin-2 (IL-2), interleukin-4 (IL-4), interleukin-10 (IL-10))2.2.4 Type of studyRandomised controlled animal trial. Randomized method, published language without restrictions.

Information sources: Seven databases were searched, including PubMed, Embase, Cochrane Library, CNKI, Wanfang Database, VIP and Chinese Medicine Database.

Main outcome(s): Overall condition: body weight, diarrhoea score Immune organ level: spleen weight, thymus weight Immune cell level: macrophage phagocytosis, Red blood cells immune complex ring rate (RBC-IC-RR), Red blood cells C3b receptor ring rate (RBC-C3b-RR), the Immunocytokine level: immunoglobulin A (SIgA), pro-inflammatory factors (tumour necrosis factor-α (TNF-α), interleukin-1β (IL-1β), interleukin-8 (IL-8), interleukin-6 (IL-6)); anti-inflammatory factors (interleukin-2 (IL-2), interleukin-4 (IL-4), interleukin-10 (IL-10)).

Quality assessment / Risk of bias analysis: The quality of included studies was reviewed using the SYRCLE risk of bias tool. The tool was used to assess recommended items in a total of ten domains from six areas." Selection bias, implementation bias, measurement bias, data integrity bias, reporting bias and other bias". For each domain, studies were rated "Y", indicating a low risk of bias; "N", indicating a high risk of bias; or "U", indicating insufficient detail in reporting.

Strategy of data synthesis: Review Manager 5.3 was used to perform the meta-analysis. Standard mean differences (SMD) were used to take into account variability in methods of animal experimentation, animal species, and study units. If $I2 \leq 50\%$ and $p > 0.1$, good homogeneity between studies was judged and a fixed-effects model was used.

Subgroup analysis: If $I2 > 50\%$ and $p \leq 0.1$, sensitivity analysis and subgroup analysis were conducted to explore the sources of heterogeneity, and a random effects model was used for results that remained highly heterogeneous. Funnel plots were used to evaluate publication bias.

Sensitivity analysis: Sensitivity analysis was performed using a random-effects model to exclude references one by one.

Country(ies) involved: China.

Keywords: Shenling Baizhu Powder; Diarrhea; Immune; cytokines.

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