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Herbal medicine for feeding intolerance with preterm infants: A systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - Without financial support.

Review Stage at time of this submission - Formal screening of search results against eligibility criteria.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 October 2023 and was last updated on 23 October 2023.

INTRODUCTION

Review question / Objective This review aims to investigate the effect of Herbal Medicine (HM) for feeding intolerance (FI) in preterm infants.

Rationale Two meta-analysis studies have been published to evaluate the effect of the intervention (probiotics, massage), and one protocol study has been published to evaluate the effect of Tuina on feeding intolerance in Complementary and Alternative Medicine. However, there is no study on the effects of herbal medicine.

Condition being studied The World Health Organization (WHO) defines preterm birth as the delivery of a live baby before 37 weeks of gestation. According to a previous review, the overall prevalence of feeding intolerance is approximately 27%. Complementary therapies, particularly herbal medicine, are frequently utilized as an alternative treatment for FI. The incomplete

development of the gastrointestinal motility system in premature infants leads to prolonged gastric emptying times and slower bowel movements, resulting in symptoms such as vomiting, abdominal distention, increased gastric retention, and weight loss.

Therefore, we conducted a meta-analysis to investigate the effectiveness of herbal medicine in treating feeding intolerance in preterm infants.

METHODS

Search strategy We will search electronically on English databases, Chinese databases and Korean databases. We used the search terms "preterm infants" and "herbal medicine," which were adapted to suit the language specifications of each database.

Participant or population [Inclusion Criteria] Preterm infants as those with a gestational age of less than 37 full weeks. [Exclusion Criteria]

Patients with gastrointestinal malformations or major organ problems, etc.

Intervention The interventions of the experimental group will include HM. Oral or nasal HM will be allowed, with no limitation on the number of herbs, formations (e.g., powder, pill, granules, capsule, decoction, oral solution, and so on), dosages and duration. And conventional treatment or basic routine treatment will be considered if the same treatment is provided in the control group.

Comparator If conventional treatment or basic routine treatment were performed in the experimental group, the same treatment should be performed in the control group.

Study designs to be included All the randomized controlled trials (RCTs) will be included.

Eligibility criteria All RCTs on the clinical effect of HM on FI in preterm infants will be included. NonRCTs, RCT protocol, animal studies, case reports, survey and reviews will be excluded.

Information sources We will electronically search 11 following databases. Three English databases (MEDLINE via PubMed, EMBASE, the Cochrane Central Register of Controlled Trials), three Chinese databases (China National Knowledge Infrastructure, Wanfang data, and VIP), and five Korean databases (such as Oriental Medicine Advanced Searching Integrated System, Korean studies Information Service System, Korea Citation Index, Research Information Sharing Service, and Korean Medical database) without any language restrictions.

Main outcome(s) 1) The time to achieve full enteral feeding (TTFEF); 2) Duration of FI; 3) Total effective rate.

Additional outcome(s) 1) The time to begin increasing weight; 2) Gastrointestinal symptoms (the time of vomiting disappearance, the time of abdominal distension disappearance, and so on); 3) Adverse events.

Quality assessment / Risk of bias analysis Quality assessment will be performed using Risk of bias (Rob2) tool from the Cochrane Handbook for Systematic Reviews of Interventions. The tool includes bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in the measurement of the outcome, and bias in the selection of reported results.

Strategy of data synthesis The data will be synthesized using Review Manager 5.4 software. Dichotomous outcomes will be summarized using Risk Ratios (RR) with 95% Confidence Intervals (CI). Continuous outcomes will be presented as the standard mean difference (SMD) or mean difference (MD) with 95% CI. Heterogeneity will be evaluated using the Higgins I² index, with I² ≥ 50% indicating potential heterogeneity, and I² ≥ 75% indicating significant heterogeneity.

Subgroup analysis If the meta-analysis demonstrates significant heterogeneity, subgroup analysis will be conducted. When a sufficient amount of data is available, subgroup analysis will be conducted based on the type of treatment (HM monotherapy vs. combination therapy) and the compositions of herbal medicines.

Sensitivity analysis A sensitivity analysis will be performed by excluding one study at a time to assess the robustness of the meta-analysis results.

Language restriction No language restriction.

Country(ies) involved South Korea.

Keywords preterm infants; feeding intolerance; herbal medicine; Systematic review; Meta-analysis.

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