

INPLASY PROTOCOL

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None declared.

Efficacy and safety of acupuncture as a treatment for low back and pelvic girdle pain during pregnancy

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Review question / Objective: This study aimed to systematically review the clinical effectiveness and safety of acupuncture as a treatment for pregnancy-related LBPGP by meta-analysis.

Condition being studied: Low back and pelvic girdle pain (LBPGP) are common during pregnancy. Analgesic drugs can be used to relieve pain but may be harmful. Acupuncture is considered to be an effective and safe therapy for pain relief. However, more evidences are needed to confirm the efficacy and safety of acupuncture as a treatment for LBPGP during pregnancy.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 November 2022 and was last updated on 21 November 2022 (registration number INPLASY2022110104).

INTRODUCTION

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acupuncture as a treatment for LBPGP during pregnancy.

METHODS

Participant or population: All pregnant women between 16~34 weeks gestation diagnosed with LBPGP.

Intervention: Treatment such as acupuncture, nonsteroidal anti-inflammatory drugs (NSAIDs), and other conventional therapy, either alone or in combination were included.

Comparator: Placebo, no treatment and standard care (SC) were included as control.

Study designs to be included: Only RCTs were eligible for inclusion. Reviews, case series, case reports, proposals, basic research, expert experience and retrospective studies were excluded.

Eligibility criteria: Types of studies: Only RCTs were eligible for inclusion. Reviews, case series, case reports, proposals, basic research, expert experience and retrospective studies were excluded. Types of participants: All pregnant women between 16~34 weeks gestation diagnosed with LBPGP were included, regardless of race, nationality, age, duration of pain, etc. Types of interventions: Treatment such as acupuncture, nonsteroidal anti-inflammatory drugs (NSAIDs), and other conventional therapy, either alone or in combination were included. Placebo, no treatment and standard care (SC) were included as control. Music therapy, psychotherapy and massage therapy were excluded.

Information sources: Databases included PubMed, EMBASE, Cochrane Library, CNKI, VIP and WanFang were searched from 1 Jan, 2000 to 31 May, 2022 for all published RCTs. Search strategies were designed with terms related to acupuncture, acupuncture therapy, pregnancy, low back pain and pelvic girdle pain, etc. There was no limitation on language of the publications. Full texts of

all relevant trials identified from the searching strategy described were screened and confirmed by two authors independently. Any disagreements were resolved through discussion or consultation with the third assessor.

Main outcome(s): Primary outcome was Visual Analogue Scale (VAS).

Additional outcome(s): Secondary outcomes included the safety relevant index such as spontaneous delivery rate, cesarean section rate, labor duration, newborn weight, newborn height, preterm birth rate, total adverse outcome rate, 12-Items Short Form Health Survey (SF-12) and Oswestry Disability Index (ODI).

Quality assessment / Risk of bias analysis: Two review authors independently assessed risk of bias for each study using the Risk of Bias 2 (RoB-2). It included 5 domains: 1) bias arising from the randomization process; 2) bias due to deviations from intended interventions; 3) bias due to missing outcome data; 4) bias in measurement of the outcome; 5) bias in selection of the reported result. Each domain was assessed as low, or high risk of bias, or can be expressed as "some concerns".

Strategy of data synthesis: Measures of treatment effect For dichotomous data, we presented results as risk ratio with 95% confidence intervals. For continuous data, we used the mean difference if outcomes were measured in the same way between trials. We calculated the standardized mean difference to combine trials that measure the same outcome by using different methods. Assessment of heterogeneity We assessed statistical heterogeneity in each meta-analysis using the T^2 , I^2 and Chi^2 statistics. We regarded heterogeneity as not important if I^2 was between 0% and 40%; moderate if I^2 was between 30% and 60%; substantial if I^2 was between 50% and 90%. When $I^2 > 50%$, a random-effects model was selected for meta-analysis, and when $I^2 < 50%$, a fixed-effect model was applied.

Subgroup analysis: We will interpret tests for subgroup differences in effects with caution given the potential for confounding with other study characteristics and the observational nature of the comparisons. In particular, subgroup analyses with fewer than five studies per category are likely to be inadequate to ascertain valid differences in effects and will not be highlighted in our results. Subgroup comparisons will not be undertaken when there are fewer than 10 studies available for meta-analysis. When subgroup comparisons are possible, we will conduct a stratified meta-analysis and a formal statistical test for interaction to examine subgroup differences that could account for effect heterogeneity. Subgroup analyses including total effectiveness rate and total adverse event rate of different severity of LBPGP patients between groups were recorded. We would report the results of subgroup analyses quoting the Chi² statistic and P value, and the interaction test I² value.

Sensitivity analysis: Given that there is no formal statistical test that can be used for sensitivity analysis, we will provide informal comparisons between the different ways of estimating the effect under different assumptions. Changes in the P values should not be used to judge whether there is a difference between the main analysis and sensitivity analysis, since statistical significance may be lost with fewer studies included.

Country(ies) involved: China.

Keywords: Acupuncture; low back and pelvic girdle pain; pregnancy, meta-analysis.

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