INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy and safety of papaverine for renal colic: A Protocol for Systematic Review and Meta-Analysis of Randomized Controlled Trials

Fang, YQ[1]; Kan, ZQ[2]; Gao, HY[3]; Wang, N[4]; Yan, WL[5]; Song, YM[6].

Review question / Objective: **The purpose of this systematic review and meta-analysis of randomized controlled trials was to evaluate the efficacy and safety of papaverine for renal colic.**
Condition being studied: **Renal colic is not an independent disease, usually refers to the sudden onset of severe pain in the kidney area caused by urinary calculi, especially ureteral calculi. The onset of the disease does not have any warning, and the pain degree can even exceed childbirth, fracture, trauma, surgery and so on. Standard analgesia is usually ineffective in patients with acute episodes of renal colic. Papaverine is a kind of alkaloid spasmolysis, which can alleviate and relieve spasm of renal pelvis and smooth muscle of renal tubules. More and more clinical studies have found that papaverine, compared with non-steroidal anti-inflammatory drugs and opioids, can effectively relieve renal colic and has the advantages of low incidence of adverse reactions and quick onset of action. Therefore, we will systematically evaluate the efficacy and safety of papaverine in the treatment of renal colic.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 May 2022 and was last updated on 17 May 2022 (registration number INPLASY202250114).

INTRODUCTION

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METHODS

Participant or population: Patients diagnosed with renal colic are of all ages, genders, and races.

Intervention: The intervention in the treatment group was papaverine alone or papaverine in combination.

Comparator: The control group used conventional analgesic program or non-steroidal anti-inflammatory drugs, opioids.

Study designs to be included: Randomized controlled trials (RCTs).

Eligibility criteria: All studies were randomized controlled trials (RCTS), regardless of language, with or without assignment concealment and blinding.Animal studies, cohort studies, case-controlled studies, case reports and expert experience will be excluded.

Information sources: PubMed, the Cochrane Library (CENTRAL), Embase, Web of Science, China National Knowledge Infrastructure (CNKI), Chongqing VIP Information (VIP), and WanFang Data, China Biomedical Literature Database (CBM), ClinicalTrials.gov and Chinese Clinical Trial Registry (ChiCTR).

Main outcome(s): The primary outcome assessed will be The degree of pain (VAS) and total effective rate.

Additional outcome(s): Secondary outcome measures include incidence of adverse reactions.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the quality of the selected studies according to the Cochrane Collaboration's tool for randomized control trials. Items will be evaluated in three categories: low risk of bias, unclear risk of bias and high risk of bias. The following seven characteristics will be assessed: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias) , selective report ing (reporting bias), and other biases. Results from these questions will be graphed and assessed using Review Manager 5.4.

Strategy of data synthesis: The meta-analysis will be performed by the Review Manager 5.4 software. The dichotomous variables will be assessed by risk ratios (RR) with 95% confidence intervals (95% CIs) and continuous variables will be analyzed with their mean difference (MD) or standard mean difference (SMD) with 95% CIs. According to the results of the heterogeneity test, random effect model or fixed effect model will be selected for data analysis. Between-study heterogeneity will be assessed using x^2 test and I^2 statistic. If $I^2<50\%$ then the fixed-effect model will be applied for data synthesis. Otherwise, the random-effect model will be conducted if the heterogeneity is significant ($I^2\geq50\%$). Outcomes will be calculated using P values and $P<0.05$ is considered statistically significant.

Subgroup analysis: If the necessary data are available, subgroup analyses will be performed to investigate differences in gender, age, papaverine dosage, etc.

Sensitivity analysis: Sensitivity analysis will be performed to assess the stability of the decision. It includes influences such as study quality, study design and sample size. In addition, we will present the results of sensitivity analysis in the summary table.

Country(ies) involved: China.

Keywords: Papaverine, Renal Colic, Systematic Review, Meta-Analysis.

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