

INPLASY PROTOCOL

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None declared.

Sinomenine hydrochloride injection for knee osteoarthritis: A protocol for systematic review and meta-analysis

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Review question / Objective: At present, many clinical studies have been reported on the treatment of KOA by injecting sinomenine hydrochloride into the knee cavity. However, no systematic evaluation has been published on this issue, and it is not clear whether sinomenine hydrochloride injection is effective and safe in the treatment of KOA. Therefore, it is important to conduct systematic evaluation to obtain relatively convincing conclusions as to whether sinomenine hydrochloride injection can be a good choice as a complementary and alternative drug (CAM) for KOA.

Condition being studied: The RCTs are eligible, whether or not the blind method is specifically described. There are no restrictions on languages. Moreover, systemic evaluation, review literature and the full article cannot be obtained will be excluded.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 November 2021 and was last updated on 09 December 2021 (registration number INPLASY2021110057).

INTRODUCTION

Review question / Objective: At present, many clinical studies have been reported on the treatment of KOA by injecting sinomenine hydrochloride into the knee cavity. However, no systematic evaluation

has been published on this issue, and it is not clear whether sinomenine hydrochloride injection is effective and safe in the treatment of KOA. Therefore, it is important to conduct systematic evaluation to obtain relatively convincing conclusions as to whether sinomenine hydrochloride

injection can be a good choice as a complementary and alternative drug (CAM) for KOA.

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METHODS

Search strategy: #1 knee osteoarthritis[Title/Abstract] | #2 osteoarthritis of knee[Title/Abstract] | #3 knee pain[Title/Abstract] | #4 knee joint osteoarthritis[Title/Abstract] | #5 knee arthritis[Title/Abstract] | #6 KOA[Title/Abstract] | #7 #1 or #2-6 | #8 sinomenine hydrochloride injection[Title/Abstract] | #9 Zhengqing Fengtongning injection[Title/Abstract] | #10 Zhengqing Fengtongning[Title/Abstract] | #11 sinomenine[Title/Abstract] | #12 #8 or #9-11 | #13 randomized controlled trial[Title/Abstract] | #14 random trials[Title/Abstract] | #15 controlled clinical trialv | #16 trials[Title/Abstract] | #17 #13 or #14-16 | #18 #7 and #12 and #17.

Participant or population: Patients should be clearly diagnosed with KOA. No restrictions on country, race, age, or gender.

Intervention: Sodium hyaluronate, triamcinolone acetonide and other drugs were injected into the joint cavity. Sodium hyaluronate, triamcinolone acetonide and other drugs were injected into the joint cavity.

Comparator: Sodium hyaluronate, triamcinolone acetonide and other drugs were injected into the joint cavity.

Study designs to be included: RCTs.

Eligibility criteria: 2.1.1. Types of studies. The RCTs are eligible, whether or not the blind method is specifically described. There are no restrictions on languages.

Moreover, systemic evaluation, review literature and the full article cannot be obtained will be excluded. 2.1.2. Types of participants. Patients should be clearly diagnosed with KOA. No restrictions on country, race, age, or gender. 2.1.3. Type of interventions 2.1.3.1. Control interventions. Sodium hyaluronate, triamcinolone acetonide and other drugs were injected into the joint cavity. 2.1.3.2. Experimental interventions. On the basis of the control group, sinomenine hydrochloride injection was combined with joint cavity injection or sinomenine hydrochloride injection was used alone. 2.1.4. Types of outcome measures 2.1.4.1 Primary outcomes. Total effective rate, Visual Analog Scale (VAS), Western Ontario and Mc Master University (WOMAC) Osteoarthritis Index. 2.1.4.2. Secondary outcomes. Circumference of knee joint, the knee joint fluid or serum interleukin-1 β (IL-1 β) level, the knee joint fluid or serum tumor necrosis factor- α (TNF- α) level, adverse events.

Information sources: PubMed, Cochrane Library, Web of Science, Embase, Allied and Complementary Medicine Database (AMED), China National Knowledge Infrastructure (CNKI), China Science and Technology Journal Database (VIP), Wanfang Database and other Chinese and English databases.

Main outcome(s): Total effective rate, Visual Analog Scale (VAS), Western Ontario and Mc Master University (WOMAC) Osteoarthritis Index.

Additional outcome(s): Circumference of knee joint, the knee joint fluid or serum interleukin-1 β (IL-1 β) level, the knee joint fluid or serum tumor necrosis factor- α (TNF- α) level, adverse events.

Data management: Two researchers will import the retrieved documents into EndnoteX9 and eliminate duplicate data.

Quality assessment / Risk of bias analysis: Bias risk assessment was conducted by two reviewers based on the bias risk assessment tool recommended in the Cochrane Manual. The details that were

assessed were as follows: (1) random sequence generation; (2) allocation concealment; (3) blinding of participants and personnel; (4) blinding of outcome assessment; (5) incomplete outcome data; (6) selective reporting; (7) other. Make: high risk, low risk, or unclear judgment for each item. Any disagreements were resolved by the third reviewer.

Strategy of data synthesis: Review Manager (Revman) (Computer program), version 5.3. (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark, 2014), was used to analyze the collected clinical research data. The enumeration data were evaluated using the relative risk (RR) and 95% confidence interval (CI), and the measurement data were combined using the standardized mean difference (SMD) and 95% CI. Analysis was performed using a fixed or random effects model according to the heterogeneity. The percentage of heterogeneity in the study was determined by the I² statistic; if the I²<50%, the heterogeneity among the included studies was considered to be small and the fixed effect model was adopted. If I²≥50%, the heterogeneity among the included studies was considered significant, and the random effect model was adopted[33]. Subgroup analysis was conducted according to different treatments in the treatment group, and sensitivity analysis was also used to analyze the sources of heterogeneity. A value P<0.10 was considered to suggest statistical heterogeneity and prompted random effects modeling.

Subgroup analysis: We will investigate the source of heterogeneity using subgroup analysis based on different interventions and controls.

Sensitivity analysis: We will carry out a sensitivity analysis to investigate the robustness and stability of outcome results by removing low methodological quality studies.

Language: Chinese and English.

Country(ies) involved: China.

Keywords: Sinomenine hydrochloride injection, knee osteoarthritis, systematic review.

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