

# INPLASY PROTOCOL

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None declared.

## INTRODUCTION

**Review question / Objective:** Baker's cyst, or Popliteal Cyst, is a fluid-filled mass that is a distention of a preexisting bursa in the popliteal fossa, most commonly the gastrocnemio-semimembranosus bursa. The purpose of this study was to evaluate

## Fire needle for Popliteal Cyst A protocol for systematic review and network meta-analysis

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**Review question / Objective:** Baker's cyst, or Popliteal Cyst, is a fluid-filled mass that is a distention of a preexisting bursa in the popliteal fossa, most commonly the gastrocnemio-semimembranosus bursa. The purpose of this study was to evaluate the efficacy and safety of fire needle in the treatment of Popliteal Cyst.

**Condition being studied:** PubMed, EMBASE, the Cochrane Library, Chinese National Knowledge Infrastructure, Chinese VIP Information, Wanfang Database, and Chinese Biomedical Literature Database.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 December 2021 and was last updated on 22 December 2021 (registration number INPLASY2021120098).

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**Rationale:** Methods: PubMed, EMBASE, the Cochrane Library, Chinese National Knowledge Infrastructure, Chinese VIP Information, Wanfang Database, and Chinese Biomedical Literature Database were searched by 2 reviewers from the

inception until December 2021. The original study that randomised control trials of fire needle for PCs will be selected and is not limited by country or language. In addition, researches in progress, the reference lists and the citation lists of identified publications will be retrieved similarly. Study selection, data extraction, and assessment of the quality will be performed independently by 2 reviewers who have been trained prior to data extraction. A meta-analysis will be conducted if the quantity and quality of the original studies included are satisfactory; otherwise, a descriptive analysis will be conducted. Review Manager V5.4: (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark) software will be used for data synthesis and assessment of the risk of bias according to the Cochrane Handbook.

**Condition being studied:** Popliteal Cyst (PCs), or Baker's cysts, are typically characterized by enlargement of the gastrocnemius-semimembranosus bursa, which communicates with the knee often through a valve-like structure associated with knee osteoarthritis or meniscus tear. The presence of a one-way valve leads to unidirectional flow of fluid from the articular cavity to the bursa. This is a fundamental factor that is involved in the formation and persistence of cysts. PCs rarely manifest alone and are most often found in conjunction with other intra-articular pathologies and inflammatory conditions, such as osteoarthritis, meniscus tears, and rheumatoid arthritis. In children, PCs are only occasionally associated with these conditions and are more often an incidental finding discovered during a routine physical examination. PCs may present as either a chronically persistent or relapsing condition or as an acute and dramatic condition that can occur in the case of cyst rupture presenting as pseudothrombophlebitis. Ultrasound and magnetic resonance imaging have proven to be consistent and accurate in the confirmation of PCs, with magnetic resonance imaging becoming the modern imaging modality of choice. Direct excision of the cyst is associated with high rates of

recurrence. In 1979, Rauschnig and Lindgren reported that the postoperative recurrence rate was as high as 63% in 40 patients who received open cyst resection via the posterior approach. Several studies have reported frequently associated intra-articular pathologies with the cysts and warned of a high recurrence rate if the intra-articular pathologic condition is not addressed. Installation of irritating substances into cystic, fluid-filled cavities, known as sclerotherapy, has a fairly long history. Agents such as ethanol, phenol, tetracycline, and group A *Streptococcus pyogenes* have all been used to sclerose cystic cavities. Sclerotherapy was used in a patient who had a meniscal tear and a recurrent symptomatic Popliteal Cyst. The Popliteal Cyst had significantly decreased in size on MRI more than 7 months after serial injection of a sclerosing agent (12.5% dextrose and morrhuate sodium). Although patients are reported to experience a positive outcome with these methods, most series are small and a higher level of evidence is needed to support this treatment as safe and effective. Use of fibrin glue as a sealant has some appeal, but this technique has yet to be supported in the literature. Currently, arthroscopic procedures are most commonly used to treat the conditions associated with PCs and to address cysts directly. Historically, open excision has resulted in unacceptably high recurrence rates. Open excision is also associated with much more morbidity and possible complications because of the need for a posterior s- or z-shaped incision in the popliteal area. In China, fire needle therapy, a type of acupuncture therapy, has been used to treat PCs. It is an external treatment method that uses a specific needle that is heated until it burns red and is quickly stabbed into diseased local lesions or acupuncture points. It could stimulate and dredge the meridians and accelerate the flow of Qi and blood thus dissipating PCs. According to published studies, fire needle can effectively relieve pain of PCs, reduce PCs size. However, there is still a lack of high-quality evidence to support the effectiveness and safety of fire needle on PCs. Based on this, we will systematically compare the efficacy and

safety of fire needle in the treatment of PCs, there by paving the way for the future treatment of PCs.

## METHODS

**Search strategy:** The two authors will independently search English databases (PubMed, Embase, and Web of Science), Chinese databases (CNKI, Wanfang database, CBM, and VIP) and clinical registration platforms (Cochrane Library, Chinese Cochrane Centre's Clinical Trial Registry Platform). The search time is from the establishment of the database to December, 2021. Boolean algorithm is used as search formula to search full-text articles with subject terms and free words. The search formula is follows: ("Popliteal Cyst" OR "Cyst, Popliteal" OR "Cysts, Popliteal" OR "Popliteal Cysts" OR "Baker's Cyst" OR "Baker Cyst" OR "Baker Cysts" OR "Cyst, Baker" OR "Cysts, Baker") AND ("Cautery" OR "(fire needle" OR "huo zhen" OR "fire needle moxibustion ") AND ("randomized controlled trial" OR "randomized" OR "placebo").

**Participant or population:** Patients with Popliteal Cyst.

**Intervention:** Types of studies. Randomized controlled trials (RCTs) with fire needle as the primary intervention for PCs will be included, and other studies such as case reports, and reviews will be excluded. No restrictions on country but language will be limited on English and Chinese.

**Comparator:** Types of comparisons. The selected RCTs should testify that the interventions were compared with a control group composed of placebo, sham acupuncture, no treatment, or other active therapies.

**Study designs to be included:** Randomized controlled trials (RCTs) with fire needle as the primary intervention for PCs will be included, and other studies such as case reports, and reviews will be excluded.

**Eligibility criteria:** Not reported.

**Information sources:** PubMed, EMBASE, the Cochrane Library, Chinese National Knowledge Infrastructure, Chinese VIP Information, Wanfang Database, and Chinese Biomedical Literature Database.

**Main outcome(s):** Of the possible cystic lesions around the knee joint, PCs are the most prevalent. PCs most commonly form by distention of the gastrocnemio-semimembranosus bursa, which is located in the medial aspect of the popliteal fossa. They often cause pain, leading to significant motor dysfunction in the affected joint, which in turn reduces the patient's quality of life. Because the pathogenesis is not clear, according to the existing treatment principles, drug treatment is mainly non-steroidal antiinflammatory drugs injection, non-drug treatment is mainly puncture aspiration, and surgical treatment. However, drug therapy is often accompanied by certain side effects, and the postoperative recurrence rate is high. As a result, many patients are looking for easier and less harmful alternatives. As an alternative therapy for external therapy, the fire needle has a history of nearly 3 thousand years in China. It can relieve pain, improve the blood circulation, stimulate metabolism of local tissue. In recent years, a certain amount of studies conducted in China have shown that compared with conventional puncture aspiration and steroid administration, fire needle has a higher cure rate for the treatment of PCs. However, the efficacy of fire needles in treating PCs has been controversial due to the lack of evidence-based medicine, and some studies have reported that acupuncture may be a placebo effect. To date, there is no reliable comprehensive review of the treatment of PCs with fire needle. We conducted this study to assess the efficacy of fire needles in the treatment of PCs and to provide clinical staff with a reliable treatment regimen. In addition, through this study, it is believed that more and higher quality original studies will be designed and carried out to provide more accurate guidance for the treatment of PCs.

**Data management:** Study selection. All reviewers undergo rigorous training prior to selecting the study. Preliminary screening of the study will be conducted by 2 reviewers independently. After searching, the duplicated studies will be removal initially from the retrieved studies by Endnote (X9). And then, 2 independent reviewers will screened titles, abstracts, and keywords of all retrieved studies for candidates according to the inclusion and exclusion criteria, we will obtain the full text of all possibly relevant studies. Excluded studies will be recorded with explanations. If it is uncertain whether to adopt because of the lack of information, XXW will try to contact authors of the original reports to obtain the information of lost. During the procedure, disagreements will be resolved by discussion or consensus with the third reviewer . Study selection will be performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses flowchart.

**Quality assessment / Risk of bias analysis:** Assessment of risk of bias.To systematically evaluate the quality of each of the studies thatfinal included. Two reviewers (SYZ and LBL) will assess the risk of bias for each included study according to the Cochrane handbook. It will eventually be rated on 3 levels (“high risk of bias”, “medium risk of bias” and “low risk of bias”). The specific evaluation items include the following 7 aspects: generation of random sequence, allocation concealment, blindness of participants, and personnel, blindness of outcome assessment, incomplete outcome data, selective reporting and other bias.

**Strategy of data synthesis:** Data synthesis and subgroup analysis.All analysis will be done through RevMan 5.4. According to heterogeneity assessment, mean difference or relative risk were calculated using fixed or random effects models. In addition, if the I<sup>2</sup>obtained after data consolidation is greater than 50% and thePvalue is less than .1, sensitivity or subgroup analysis will be performed to exclude the source of heterogeneity. If the included original

research data is insufficient for quantitative analysis, the review will only represent, and summarize the evidence.

**Subgroup analysis:** Outcomes.Primary outcome: effective rate and the cyst diameter. Secondary outcomes: recurrence rate; adverse events incidence caused by fire needle, such as dizziness, vomiting, weariness, etc.

**Sensitivity analysis:** Sensitivity analysis.If the results show significant heterogeneity and the number of included studies is sufficient, sensitivity analysis will be performed to identify the quality and robustness of the meta-analysis result, which includes assessing the impact of sample size, methodological elements and the characteristic of research, and missing data.

**Country(ies) involved:** China.

**Keywords:** acupuncture, fire needle, Popliteal Cyst, protocol, systematic review.

**Contributions of each author:**

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