INPLASY PROTOCOL

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Corresponding author:
Nian Zeng

fhzengnian@163.com

Author Affiliation:
Medical Community of Fenghua District Hospital of Traditional Chinese Medicine of Ningbo.

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Conflicts of interest:
None declared.

Efficacy and safety of steroid injections for lower limb tendinopathy: a protocol of systematic review

Zeng, N[1]; Wang, YY[2]; Li, M[3]; Qiu, HJ[4].

Review question / Objective: **The aim of this review is to evaluate the clinical efficacy and safety of steroid injections for patients with lower limb tendinopathy.**
Condition being studied: **Tendinopathies are clinically characterized by localized, painful, and tender tendon thickening, causing dysfunction. Lower limb tendinopathies, including greater trochanteric pain syndrome (GTPS), patellar tendinopathy (PT), and Achilles tendinopathy (AT), are prevalent among both athletes and sedentary patients. This disease are often difficult to treat, sporting activity, physical activity and profession substantially impacted. There are a great variety of potential treatment, including surgical intervention, pain relieving medications, non-steroidal anti-inflammatory drugs, steroid injections and physical therapy. Limited evidence suggests steroid injections may be beneficial for this disease.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 August 2021 and was last updated on 08 August 2021 (registration number INPLASY202180025).

INTRODUCTION

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METHODS

Participant or population: Greater trochanteric pain syndrome(GTPS), patellar tendinopathy (PT), and achilles tendinopathy (AT) patients will be included with their standard diagnostic criteria. There are no limits to research subjects' age, gender, race, condition duration or intensity.

Intervention: The treatment group will be treated with steroid injection. Mixed therapies including steroid injection will be excluded.

Comparator: The control group will adopt the internationally recognized therapy such as placebo, “wait and see”, NSAIDs or physiotherapy. Steroid injections with another active therapy versus the same therapy alone will also be investigated.

Study designs to be included: Only randomized controlled clinical trials (RCTs) related to the effects of steroid injections for treating lower limb tendinopathy will be included in this systematic review. Trials published in the form of dissertations will be also selected as eligible studies.

Eligibility criteria: Interventions will include any steroid injections for lower limb tendinopathyshoulder pain patients.

Information sources: Relevant studies will be searched from the databases of PubMed, EMBASE, Cochrane Library, China Knowledge Resource Integrated Database, Weipu Database for Chinese Technical Periodicals, SinoMed, and Wanfang Database.

Main outcome(s): The main outcomes will be clinical outcomes, such as the Victorian Institute of Sport Assessment (VISA) questionnaire (VISA-A,VISA-P and VISA-G for Achilles, patellar and greater trochanteric pain syndrome, respectively) and pain measured with scales or questionnaires, and performance outcomes, such as strength or jumping tests.

Additional outcome(s): Adverse effects.

Quality assessment / Risk of bias analysis: We will use the Cochrane Collaboration's tool which is recommended by the Cochrane Reviewer’s Handbook to assess risk of bias for quality assessment of the included studies. The studies will be graded based on: (i) random sequence generation; (ii) allocation concealment; (iii) blinding; (iv) incomplete outcome data; (v) selective outcome reporting; (vi) other sources of bias.

Strategy of data synthesis: The data of the study included may be divided into two cases, depending on whether the data are suitable for meta-analysis. If the meta-analysis will not be performed because of heterogeneity, interventions, comparisons, outcomes etc, we will make forms for a qualitative description. A meta- analysis will be performed if there are two or more studies of sufficient homogeneity across the outcomes measures to ensure pooling. For dichotomous data, we will present the results as risk ratios (RR) with 95% confidence intervals (CIs). For continuous data, the mean difference (MD) will be included in. If outcome variables were measured on different scales, standard mean differences (SMD) analysis with 95% CIs will be included in the meta-analysis. Heterogeneity will be analyzed using the I2 statistic. A value of >25% will be considered a sign of low heterogeneity, >50% a sign of moderate heterogeneity and >75% a sign of high heterogeneity. If possible, subgroup analysis will be developed and publication bias will be

assessed using a funnel plot graph. If there is no statistic heterogeneity among the results, the fixed effects model will be employed for meta-analysis. If there is a statistic heterogeneity, the source of the heterogeneity should be further analyzed. If there is obvious clinical heterogeneity, the subgroup or sensitivity analysis, or only descriptive analysis can be performed.

Subgroup analysis: If there is a significant heterogeneity in the included trials, we will conduct subgroup analysis.

Sensitivity analysis: When there are sufficient studies, we will carry out sensitivity analysis to test the robustness of studies according to the quality of method, the sample size and the selection of missing data. And the fluctuation of results will be observed.

Language: Without any language or publication status restrictions.

Country(ies) involved: China.

Keywords: steroid injections, lower limb tendinopathy, protocol, systematic review.

Contributions of each author:
Author 1 - Nian Zeng - The author drafted the manuscript.
Author 2 - Yueyi Wang - The author provided statistical expertise and contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 3 - Ming Li - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 4 - Hanjun Qiu - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.