INPLASY PROTOCOL

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**Review Stage at time of this submission:** **The review has not yet started.**

**Conflicts of interest:** **None.**

# Efficacy of repair and reconstruction therapy for the treatment of lateral ankle ligament injury: A protocol of systematic review and meta-analysis

Wang ZG[1]; Wu C [2].

**Review question / Objective:** **Can repair and reconstruction therapy (RRT) effectively treat lateral ankle ligament injury (LALI)?**
**Condition being studied:** **Repair and reconstruction therapy; lateral ankle ligament injury.**
**Information sources:** **All information sources will be searched from inception to the March 1, 2020 with no restrictions of language and publication status. The following databases will be utilized for searching: MEDLINE, EMBASE, Web of Science, Cochrane Library, PsycINFO, China National Knowledge Infrastructure. Specific search strategy using searching terms has been used to database MEDLINE. We will also adapt similar detailed search strategies to the other electronic databases. In addition, we will also plan to search grey literatures, such as Opengrey, dissertations, conference abstracts, and reference lists of relevant reviews.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 April 2020 and was last updated on 14 April 2020 (registration number INPLASY202040082.

## INTRODUCTION

**Review question / Objective:** **Can repair and reconstruction therapy (RRT) effectively treat lateral ankle ligament injury (LALI)?**

**Condition being studied:** **Repair and reconstruction therapy; lateral ankle ligament injury.**

## METHODS

**Participant or population:** **We will include any participants who were diagnosed as LALI, regardless their country, background, race, sex, and age.**

**Intervention:** **In the experimental group, the intervention of interest is the use of RRT for the treatment of patients with LALI.**

**Comparator:** In the control group, comparators can be any treatments, except the RRT.

**Study designs to be included:** We will include randomized controlled trials (RCTs) that assessing the efficacy and safety of RRT for patients with LALI.

**Eligibility criteria:** We will include RCTs that compared the efficacy and safety of RRT to other treatments for patients with LALI.

**Information sources:** All information sources will be searched from inception to the March 1, 2020 with no restrictions of language and publication status. The following databases will be utilized for searching: MEDLINE, EMBASE, Web of Science, Cochrane Library, PsycINFO, China National Knowledge Infrastructure. Specific search strategy using searching terms has been used to database MEDLINE. We will also adapt similar detailed search strategies to the other electronic databases. In addition, we will also plan to search grey literatures, such as Opengrey, dissertations, conference abstracts, and reference lists of relevant reviews.

**Main outcome(s):** The primary outcome includes pain intensity. It was measured by any pain scales, such as Visual Analogue Scale.

**Additional outcome(s):** The secondary outcomes comprise of ankle function after ligament injury (measured by Karlsson scoring scale or other scales), time to return to work (days or weeks or months), time to return to sports (days or weeks or months), Tegner activity level, quality of life (measured by Global Quality of Life Scale, or other indexes), and adverse events.

**Data management:** Data will be collected by two independent investigators using a previous created and standardized data collection sheet. Any discrepancies between two investigators will be settled down by a third experienced investigator through discussion. The collected information includes title, first author, year of publication, study design, study setting, patient characteristics, inclusion and exclusion criteria, diagnostic criteria, sample size calculation, details of intervention and controls, outcomes, any expected or unexpected adverse events, and funding information. Whenever there is insufficient information, we will contact original authors to inquire it.

**Quality assessment / Risk of bias analysis:** Study quality will be assessed by two independent investigators with Cochrane Risk of Bias Tool. It is designed for use within all RCTs, and each study will be assessed on seven aspects according to the guidelines of Cochrane Handbook for Systematic Reviews of Interventions. Using the guidelines, all included studies will be graded as low, unclear or high risk of bias. Any different opinions between two investigators will be solved by a third investigator through discussion.

**Strategy of data synthesis:** We will undertake statistical analysis using RevMan 5.3 software. We will express continuous outcome values with mean difference or standardized mean difference and 95% confidence intervals, and dichotomous outcome values with risk ratio and 95% confidence intervals. A statistical test of heterogeneity will be performed using $I^2$ statistic. $I^2 \leq 50$ means low heterogeneity, and a fixed-effects model will be used; while $I^2 > 50\%$ indicates significant heterogeneity, and a random-effects model will be utilized. If there is low heterogeneity among sufficient included studies, we will plan to conduct meta-analysis if it is possible. On the other hand, if there is substantial heterogeneity, we will perform subgroup analysis to check the possible causes for such significant heterogeneity. In addition, we will also present narrative summary according to the different study characteristics, patient characteristics, details of intervention and control, and outcome measurements.

**Subgroup analysis:** We will carry outcome subgroup analysis based on the different types of study characteristics, study quality, treatments, and controls.

**Sensibility analysis:** We will also perform sensitivity analysis to explore the robustness of pooled results by excluding low quality studies.

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

**Keywords:** Repair and reconstruction therapy; lateral ankle ligament injury; efficacy.