

# INPLASY PROTOCOL

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**Support:** No

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

**Conflicts of interest:**  
None.

## The adverse effects of novel coronavirus on diabetic foot patients: protocol for a systematic review and meta-analysis

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**Review question / Objective:** Does novel coronavirus pneumonia affect the clinical efficacy of diabetic foot patients. **Condition being studied:** The number of novel coronavirus infections worldwide has been increasing. There is no effective treatment or vaccine. The diabetes is the most common chronic disease and frequently occurring disease. The risk of infection with new coronavirus is high. The diabetic foot infection may increase the mortality of COVID-19. At present, there is no correlation between the infection of diabetic foot and the adverse outcomes of COVID-19 at home and abroad. However, this is a problem that can not be ignored.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 August 2020 and was last updated on 27 August 2020 (registration number INPLASY202080113).

### INTRODUCTION

**Review question / Objective:** Does novel coronavirus pneumonia affect the clinical efficacy of diabetic foot patients.

**Condition being studied:** The number of novel coronavirus infections worldwide has been increasing. There is no effective

treatment or vaccine. The diabetes is the most common chronic disease and frequently occurring disease. The risk of infection with new coronavirus is high. The diabetic foot infection may increase the mortality of COVID-19. At present, there is no correlation between the infection of diabetic foot and the adverse outcomes of

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COVID-19 at home and abroad. However, this is a problem that can not be ignored.

## METHODS

**Search strategy:** Two researchers independently screened literature, extracted data and cross checked them. In case of any difference, it shall be settled through discussion or consultation with a third party. In the process of literature selection, the first step is to read the title. After excluding the obviously irrelevant literature, the second step is to read the abstract and the full text to determine whether to include it. If necessary, contact the author of the original study by email or phone to obtain the uncertain but very important information for this study. The content of data extraction includes: 1. Basic information: the first author, publication time, research location, sample size, sex ratio, age, research type; 2. Outcome indicators of concern; 3. Relevant elements of bias risk assessment.

**Participant or population:** Novel coronavirus pneumonia with diabetic foot will be included in our study. There are no restrictions on the region, gender and age of patients.

**Intervention:** This study will investigate a comparison of patients with diabetic foot with covid-19 and non-diabetic foot with covid-19. According to whether diabetic foot is combined, they are divided into diabetic foot group (trail) and non diabetic foot group (comparison). Patients who novel coronavirus pneumonia without foot disease will be excluded.

**Comparator:** Diabetic foot patients without novel coronavirus pneumonia.

**Study designs to be included:** Randomized controlled trials and non randomized controlled trials.

**Eligibility criteria:** Novel coronavirus pneumonia with diabetic foot patient will be included in our study. There are no restrictions on the region, gender and age of patients.

**Information sources:** We will search each database from the built-in until April 2021. The English literature mainly searches Cochrane Library, PubMed, EMBASE, and Web of Science, while the Chinese literature comes from CNKI, CBM, VIP, and Wangfang database. Simultaneously we will retrieval clinical registration tests and grey literatures, and he researches related to the adverse effects of novel coronavirus on diabetic foot were collected. The two researchers worked independently on literature selection, data extraction, and quality assessment. The dichotomous data is represented by relative risk (RR), and the continuous is expressed by mean difference (MD) or standard mean difference (SMD), eventually the data is synthesized using a fixed effect model (FEM) or a random effect model (REM) depending on whether or not heterogeneity exists. The primary outcome were clinical response rate, C-reactive protein and procalcitonin. Secondary outcomes are mainly include mortality, amputation rate, wound healing time and nerve conduction velocity. Finally, meta-analysis was conducted by RevMan software version 5.3.

**Main outcome(s):** Clinical effective rate of diabetic foot patients, C-reactive protein, Procalcitonin.

**Additional outcome(s):** Mortality, amputation rate, wound healing time, nerve conduction velocity.

**Quality assessment / Risk of bias analysis:** The two researchers independently assessed the bias risk of the included studies with the NOS scale, and cross checked the results.

**Strategy of data synthesis:** Data analysis will be conducted in Review Manager Version 5.3 and Stata 14.0 software for Mac. The risk ratio (RR) was used as the analysis statistic and 95% CI was provided. The heterogeneity of the results was analyzed by  $\chi^2$  test (the test level was  $\alpha = 0.1$ ), and the degree of heterogeneity was determined by  $I^2$ . If there is no statistical

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heterogeneity between the results of each study, the fixed effect model is used for Meta-analysis; if there is statistical heterogeneity between the results of each study, the source of heterogeneity is further analyzed. After excluding the influence of obvious clinical heterogeneity, the random effect model is used for Meta-analysis. The level of Meta-analysis is set as  $\alpha = 0.05$ . Significant clinical heterogeneity was treated by subgroup analysis or sensitivity analysis, or only descriptive analysis.

**Subgroup analysis:** A subgroup analysis will be performed to determine the potential heterogeneity and inconsistency clinically and statistically, and will include age, gender and disease duration of patients and so on. A meta-regression analysis will be implemented to quantify the inter-subgroup difference and explore statistical significance.

**Sensibility analysis:** To ensure the stability of the results, we will conduct sensitivity analysis of the results by excluding each of the studies included in the analysis one by one, then re-analyzing the results, and comparing the differences between the re-obtained results and the original results. In this way, we will be able to assess the impact of individual studies on overall outcomes and their robustness.

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

**Keywords:** Novel coronavirus pneumonia, Meta-analysis, diabetic foot disease, adverse outcome, systematic review.

**Contributions of each author:**

Author 1 - DongQiong Chen.

Author 2 - Hui Zhou.

Author 3 - Yan Yang.