INPLASY PROTOCOL

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

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

# Effect of intraoperative pressure ulcer preventive nursing on inflammatory markers in patients with high-risk pressure ulcers: A protocol of systematic review and meta-analysis

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**Review question / Objective:** **Can intraoperative pressure ulcer preventive nursing (IPUPN) affect on inflammatory markers (IMs) in patients with high-risk pressure ulcers (HRPU)?**
**Condition being studied:** **Pressure ulcer; preventive nursing; AND inflammatory markers.**
**Information sources:** **We will carry out a rigorous literature search from Cochrane Library, MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, and Chinese Biomedical Literature Database. We will search all those electronic databases from inception to the March 1, 2020 with no restrictions of language and publication status. The search strategy sample for Cochrane Library will be created. We will also build similar search strategies for other electronic databases. In addition to the electronic databases, we will also examine clinical trial registries, dissertations, informal publication, and reference lists of all relevant reviews.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 April 2020 and was last updated on 05 April 2020 (registration number INPLASY202040029).

## INTRODUCTION

**Review question / Objective:** **Can intraoperative pressure ulcer preventive nursing (IPUPN) affect on inflammatory markers (IMs) in patients with high-risk pressure ulcers (HRPU)?**

**Condition being studied:** **Pressure ulcer; preventive nursing; AND inflammatory markers**

## METHODS

**Participant or population:** Any participants (18 years old or over) who have been diagnosed as HRPU and received IPUPN will be included in spite of race, nationality, and sex.

**Intervention:** All patients in the experimental group were treated with any types of IPUPN.

**Comparator:** Comparison interventions could be placebo, sham intervention, conventional pharmacological treatments, and any other management. However, patients who also received IPUPN will be excluded.

**Study designs to be included:** This study will only include high quality randomized controlled trials (RCTs) that assessed the effects and harms of IPUPN on IMs in patients with HRP.

**Eligibility criteria:** This study will include RCTs that compared the effects and harms of IPUPN vs. any management on IMs in patients with HRPU.

**Information sources:** We will carry out a rigorous literature search from Cochrane Library, MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, and Chinese Biomedical Literature Database. We will search all those electronic databases from inception to the March 1, 2020 with no restrictions of language and publication status. The search strategy sample for Cochrane Library will be created. We will also build similar search strategies for other electronic databases. In addition to the electronic databases, we will also examine clinical trial registries, dissertations, informal publication, and reference lists of all relevant reviews.

**Main outcome(s):** The primary outcomes include IMs (such as C-reactive protein, white blood cell count and body temperature), and incidence of new pressure ulcers (the proportion of participants developing any new pressure ulcer/s of any grade).

**Additional outcome(s):** The secondary outcomes consist of time to ulcer development, quality of life as assessed by a validated tool, patient length of hospital stay (days or weeks), and adverse events.

**Data management:** After study selection, data will be extracted based on the predefined standard data extraction form. Two investigators will independently extract the data from all included trials. Any disagreements between two investigators will be solved through discussion or consultation by a third investigator. The extracted information includes study demographic information (such as first author, publication time, and country), patient characteristics (such as gender, age, and number of patients), study methods (such as study setting, randomization, and blind), interventions and comparators (such as types of therapies, dosage, and duration), outcomes (such as primary, secondary, and harm measurements), and other information (such as funding information).

**Quality assessment / Risk of bias analysis:** Two investigators will appraise the risk of bias for each included trial using Cochrane risk of bias tool, which consists of seven different items. Each one is judged as low risk of bias, unclear risk of bias, and high risk of bias. Any opposition between two investigators will be settled down by a third investigator through discussion.

**Strategy of data synthesis:** If $I^2$ ≤50% and sufficient data are collected on the same outcome measurement, we will carry out a meta-analysis if necessary. Otherwise, if $I^2$ >50%, subgroup analysis will be conducted, and data will be synthesized more cautiously. If there is still substantial heterogeneity after subgroup analysis, the outcome data will not be suitable for pooling quantitative synthesis. Under such situation, we will report a narrative description with the information in the text to summarize and elaborate the

characteristics and finding of individual trials.

**Subgroup analysis:** Subgroup analysis will be carried out to explore the causes of significant heterogeneity based on the different study or patient characteristics, treatment and control types, and outcome measurements.

**Sensibility analysis:** When there are adequate trials, we will conduct sensitivity analysis to check the robustness and stability of conclusions by excluding low quality studies.

**Countries involved:** China

**Keywords:** Pressure ulcer; preventive nursing; inflammatory markers; effects; safety.