

# INPLASY PROTOCOL

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

**Conflicts of interest:**  
None declared.

## Bleeding risk of anticoagulant therapy in patients with advanced cancer in palliative care settings: a protocol for systematic review and meta-analysis

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**Review question / Objective:** The systematic review aim to provide synthesised and appraised evidence to assess the bleeding risk of anticoagulant therapy in patients with advanced cancer in palliative care settings.

**Condition being studied:** Cancer is a recognized risk factor for venous thromboembolism (VTE). The main forms of thromboembolic disease include pulmonary embolism (PE) and deep vein thrombosis (DVT). Given their diagnosis and often poor physical status, patients with advanced cancer are at particularly high risk of developing VTE, resulting in reduced activity levels or even immobility. The exact incidence and prevalence of VTE in the population of cancer patients receiving hospice or palliative care has not been well investigated and few reports are available. Clinical studies have not yet determined whether such patients benefit from anticoagulant therapy and whether there is an increased risk of bleeding and death.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 April 2022 and was last updated on 11 April 2022 (registration number INPLASY202240064).

### INTRODUCTION

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therapy in patients with advanced cancer in palliative care settings.

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## METHODS

**Participant or population:** Patients with advanced cancer in palliative care settings will be included. There will also be no limitations related to age, sex, disease duration.

**Intervention:** Patients treated with anticoagulation, including low-molecular-weight heparin (LMWH) or warfarin, etc.

**Comparator:** The control group adopts conventional nursing and symptomatic treatment.

**Study designs to be included:** RCT.

**Eligibility criteria:** Patients with advanced cancer in palliative care settings will be included. There will also be no limitations related to age, sex, disease duration.

**Information sources:** Relevant studies will be searched in the following electronic databases from their inception to April 1, 2022: PubMed, Web of Science, Medline, EMBASE, Cochrane Library, China Knowledge Resource Integrated Database (CNKI), Weipu Database for Chinese Technical Periodicals (VIP), SinoMed (CBM), and Wanfang Database.

**Main outcome(s):** Incidence of bleeding events including subcutaneous bleeding, gastrointestinal bleeding, etc.

**Quality assessment / Risk of bias analysis:** Two researchers will assess the risk of bias of included studies independently according to the Cochrane collaboration's tool. The tool comprise 7 aspects which are random sequence generation, allocation concealment, the blinding method for patients, researchers and outcomes assessors, incomplete outcome data, and selective reports. Every risk of bias will be classified as low, unclear, and high.

**Strategy of data synthesis:** RevMan V.5.3 software will be used in data synthesis. We will express dichotomous data in RR and continuous data in mean difference (MD) or standardized mean difference (SMD). The fixed-effect model will be put into use if  $I^2 \leq 75\%$ ,  $I^2 > 75\%$  will be classified as having high heterogeneity. When  $I^2 > 75\%$ , we will then perform a subgroup analysis or a sensitivity analysis. RevMan V.5.3 software will be used in data synthesis. We will express dichotomous data in RR and continuous data in mean difference (MD) or standardized mean difference (SMD). The fixed-effects model will be put into use if  $I^2 \leq 75\%$ , and we will then offer a descriptive analysis or subgroup analysis.

**Subgroup analysis:** If there is a significant heterogeneity in the included studies, subgroup analysis will be performed to detect the substantial heterogeneity based on the different anticoagulants.

**Sensitivity analysis:** When there are sufficient studies, sensitivity analysis will be performed to assess the robustness of studies according to methodological quality, sample size, and missing data.

**Language:** No restriction.

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

**Keywords:** Advanced cancer; Palliative care; Anticoagulant therapy; Systematic review; protocol.

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