INPLASY

INPLASY202550083

doi: 10.37766/inplasy2025.5.0083

Received: 27 May 2025

Published: 27 May 2025

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Cerebral Outcomes of Warfarin Versus Non-Vitamin K Antagonist Therapy for Atrial Fibrillation: A Systematic Review and Meta- Analysis of Randomized Controlled Trials

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202550083

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 May 2025 and was last updated on 27 May 2025.

INTRODUCTION

Review question / Objective To comprehensively evaluate the existing evidence regarding the management of Atrial Fibrillation with Warfarin vs Non-Vitamin K antagonists and assess the Cerebral outcomes (including stroke occurrence and cognitive function).

Condition being studied Cerebral outcomes in patients with Atrial Fibrillation.

METHODS

Participant or population Patients with Atrial Fibrillation who were managed with Warfarin or Non-Vitamin K antagonists.

Intervention Patients with Atrial Fibrillation who were managed with Non-Vitamin K antagonists.

Comparator Patients with Atrial Fibrillation who were managed with Warfarin.

Study designs to be included Randomized Controlled Trials only.

Eligibility criteria
Inclusion:
• Studies published from inception to June 2024 will be included in the review.
• Studies that reported the number of patients managed with Warfarin or Non-Vitamin K antagonists for their Atrial Fibrillation will be included.
• Only studies published in the English language will be included.
• The review will include studies with adult patients.
• The included studies reported outcomes of interest relevant to the clinical question.
• The following study types will be included in the review: RCTs (randomized controlled trials).

Exclusion:
• Studies published in languages other than English.
• Studies that did not report outcomes of interest for the clinical question.

• Studies that included pediatric patients or patients under 18 years old.
• Studies that did not use Warfarin or Non-Vitamin K antagonists as a treatment for Atrial Fibrillation.
• Studies other than RCTs.
• Studies with a high risk of bias or low quality based on the assessment of study design, sample size, data collection and analysis, and other relevant factors.

Information sources
Electronic databases:
• PubMed.
• Embase.
• Cochrane.
• Global Health.

Main outcome(s)
Primary objectives:

1. Evaluate the effectiveness of Warfarin vs Non-Vitamin K antagonists' therapy in reducing death and hospitalization and improving the overall outcomes of Atrial Fibrillation treatment.

2. Assess the occurrence of stroke in Atrial Fibrillation patients on Warfarin vs Non-Vitamin K antagonist therapy.

Additional outcome(s)
Secondary objectives:

1. Identify any factors (including concurrent co-morbidities and other conditions) that may influence the effectiveness of Warfarin vs Non-Vitamin K antagonist therapy.

2. Identify any gaps in the current literature on the use of Warfarin vs Non-Vitamin K antagonist therapy in managing patients with Atrial Fibrillation and provide recommendations for future research.

Data management The outputs of electronic database searches will be transferred to RAYYAN Software for the purposes of screening and selection. Two authors will individually assess the titles and abstracts of all studies identified in the database search to identify potentially eligible studies. We will retrieve the full-text articles for studies that meet the inclusion criteria, and then two authors will independently screen 100% of the full-text articles to determine eligibility. In case of disagreements, the senior author will be consulted to help resolve the issue. We will document the screening process, including reasons for exclusion, using a PRISMA flow diagram.

Quality assessment / Risk of bias analysis The protocol will define the method of literature critique/appraisal use and will use the Cochrane Risk of Bias tool (RoB2) for relevant content and methodology used in each of the papers to be reviewed.

Strategy of data synthesis Narrative synthesis will be done alongside any meta-analysis and will be carried out using a framework which consists of four elements:
1. Developing a theory of how the intervention works, why, and for whom.
2. Developing a preliminary synthesis of findings of included studies
3. Exploring relationships within and between studies.
4. Assessing the robustness of the synthesis.

Subgroup analysis Four authors will collectively extract data from the selected papers of the systematic review, while two authors will analyze information in RevMan 5.3 statistical software. In addition, heterogeneity will be explored.

Sensitivity analysis We will perform sensitivity analyses by excluding studies at high risk of bias, unpublished studies, or studies with imputed data to assess the robustness of the pooled effect estimates.

Country(ies) involved Kingdom of Saudi Arabia.

Keywords ("Warfarin") AND ("NOAC") AND ("Acute Ischemic Stroke" OR "Stroke")AND ("Atrial Fibrillation" OR "AFib") AND ("RCT" OR "RandomizedControlled Trials").

Contributions of each author
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