RobotReviewer report

Apixaban to Prevent Venous Thromboembolism in Patients with Cancer

Risk of bias table

trial	design	n	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
Carrier M, 2019	RCT	1255	+	+	+	?

Characteristics of studies

Carrier M, 2019

Population	1. Trial Population Patients who had a newly diagnosed cancer or progression of known cancer after complete or partial remission and who were initiating a new course of chemotherapy with a minimum treat- ment intent of 3 months were potentially eligible. 2. Other exclusion criteria included the use of medica- tions contraindicated with apixaban, pregnancy or potential pregnancy, breast-feeding, the use of continuous anticoagulation, and a weight of less than 40 kg. 3. We conducted the Apixaban for the Prevention of Venous Thromboembolism in High-Risk Ambu- latory Cancer Patients (AVERT) trial to assess the efficacy of apixaban thromboprophylaxis in am- bulatory patients with cancer at intermediate-to-high risk for venous thromboembolism (Khorana score, ,â•2).
Intervention	1. The experimental group received Apixaban to Prevent Venous Thromboembolism apixaban at a dose of 2.5 mg twice daily, and the control group received identical placebo tablets twice daily; the treatment period was 180 days. 2. Randomization and Trial Intervention Eligible patients underwent randomization by means of a centralized, Web-based randomization system to receive apixaban or placebo in a 1:1 ratio. 3. The AVERT trial was a randomized, placebo- controlled, double-blind clinical trial comparing apixaban (2.5 mg twice daily) with placebo.
Outcomes	1. The primary efficacy outcome was the first epi- 2. 13 Other safety outcomes included clinically relevant non- major bleeding (see the Supplementary Appen- dix) and overall survival during the trial period. 3. Other exclusion criteria included the use of medica- tions contraindicated with apixaban, pregnancy or potential pregnancy, breast-feeding, the use of continuous anticoagulation, and a weight of less than 40 kg.

Bias	Judgement	Support for judgement
Random sequence generation	low	1. Randomization was stratified according to age, sex, and participating center and occurred up to 5 days before the administration of the first chemotherapy.

		2. Randomization and Trial Intervention Eligible patients underwent randomization by means of a centralized, Web-based randomization system to receive apixaban or placebo in a 1:1 ratio. 3. Data were collected at the sites and entered in an online database managed by the Methods Cen- tre of the Ottawa Hospital Research Institute.
Allocation concealment	low	1. Randomization was stratified according to age, sex, and participating center and occurred up to 5 days before the administration of the first chemotherapy. 2. Randomization and Trial Intervention Eligible patients underwent randomization by means of a centralized, Web-based randomization system to receive apixaban or placebo in a 1:1 ratio. 3. Data were collected at the sites and entered in an online database managed by the Methods Cen- tre of the Ottawa Hospital Research Institute.
Blinding of participants and personnel	low	1. The experimental group received Apixaban to Prevent Venous Thromboembolism apixaban at a dose of 2.5 mg twice daily, and the control group received identical placebo tablets twice daily; the treatment period was 180 days. 2. A central adjudication committee whose members were unaware of the treatment assignments re- viewed all suspected outcome events. 3. The AVERT trial was a randomized, placebo- controlled, double-blind clinical trial comparing apixaban (2.5 mg twice daily) with placebo.
Blinding of outcome assessment	high/unclear	1. All trial outcomes were adjudicated by an in- dependent adjudication committee whose mem- bers were unaware of the treatment assignments. 2. The AVERT trial was a randomized, placebo- controlled, double-blind clinical trial comparing apixaban (2.5 mg twice daily) with placebo. 3. A central adjudication committee whose members were unaware of the treatment assignments re- viewed all suspected outcome events.

References

1. Carrier M et al. Apixaban to Prevent Venous Thromboembolism in Patients with Cancer N. Engl. J. Med. 2019. 8(10); 711-719 PMID: 15758007