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CANVAS Trial (AFT-28)

DOACS versus LMWH +/- Warfarin for VTE in Cancer: A Randomized Effectiveness Trial

Co-Chairs: Jean Connors MD & Deborah Schrag MD MPH
Dana-Farber Cancer Institute, Boston, MA

National Blood Clot Alliance

TAP TO RETURN TO KIOSK MENU

- Cancer patients are at risk for VTE (venous thromboembolism).
- Anticoagulation therapy is necessary to prevent recurrent VTE.
- Current practice patterns are a hybrid use of LMWH+/-warfarin.
- Recently, the FDA has approved 4 Direct Oral Anticoagulants (DOACs) for VTE based on efficacy trials showing noninferiority to warfarin.
- Given the myriad exclusion criteria present in efficacy trials, more evidence is needed to inform the

Effectiveness of DOACs in cancer

Aim 1: To compare the **effectiveness** of anticoagulation with a DOAC (intervention) with LMWH/warfarin (comparator) for preventing VTE recurrence in patients with cancer.

Aim 2: To compare the **harms** of DOAC vs. LMWH/warfarin therapy for cancer patients with VTE based on the cumulative rate of major bleeding at 6 months.

Aim 3: To compare the impact of DOAC vs. LMWH/warfarin therapy on the **experience and burden** of anticoagulation therapy for cancer patients with VTE.

Aim 4: To compare the impact of DOAC vs. LMWH/warfarin therapy on **mortality** in cancer patients with VTE

RATIONALE **OBJECTIVE**

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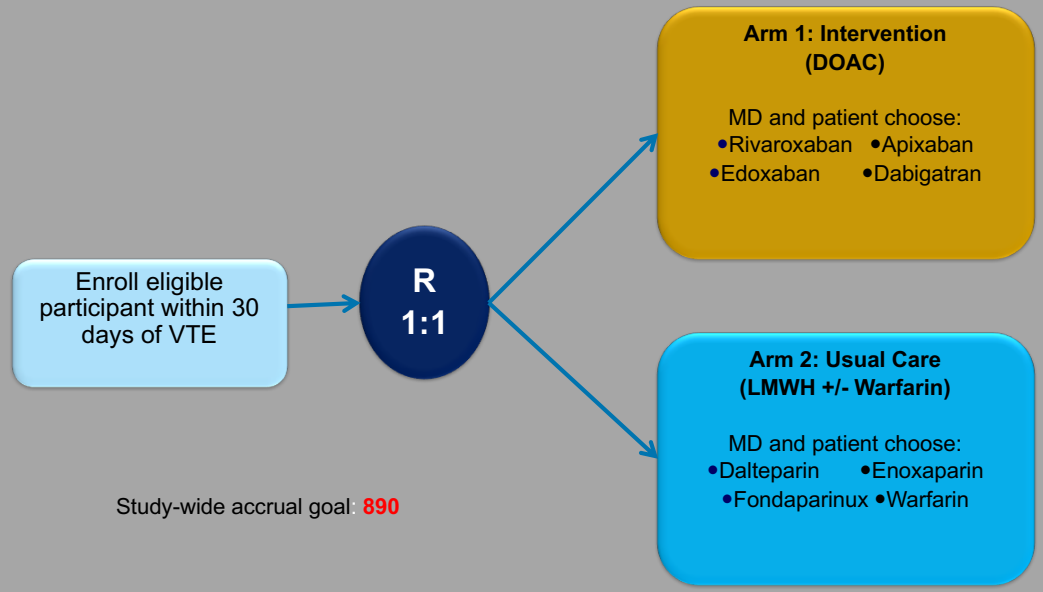
TAP TO RETURN TO KIOSK MENU

- rationale/ objective
- study schema
- treatment plan/ intervention
- key eligibility criteria
- follow up



STUDY SCHEMA

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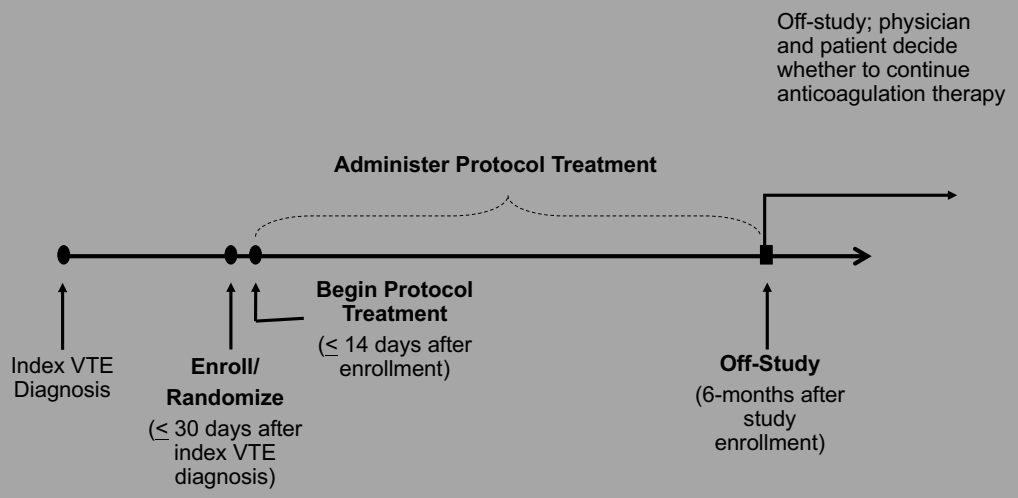

TREATMENT PLAN / INTERVENTION

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rationale/ objective

study schema

treatment plan/ intervention

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follow up

Inclusion

- **Cancer Diagnosis**
  - Diagnosis of an **advanced** solid tumor, lymphoma, chronic lymphocytic leukemia (CLL), or myeloma (no time restrictions or limitations) **–OR–** diagnosis of **early** stage solid tumor cancer, lymphoma, chronic lymphocytic leukemia (CLL), or myeloma ≤ 12 months prior to study enrollment.
- **VTE within 30 days**
  - Diagnosis may be made based on physical exam or imaging studies. Participants with both symptomatic and asymptomatic VTEs are eligible.
  - Any anticoagulation drug/strategy may be used to treat the index VTE; protocol treatment will begin ≤ 14 days after enrollment.
  - Intend anticoagulation therapy for >= 3 mo.
- Age ≥ 21 years.
- Platelet > 50,000/mm^3
- CrCl > 15 ml/min

Exclusion

- Acute leukemia
- Past, present, or future alloHSCT
- Present or future autoHSCT
- Significant bleeding
- Ongoing P-gp inhibitor or azole antifungals
- Pregnant/nursing

1^O Cumulative VTE **recurrence** at 6 months
2^O Cumulative rates major **bleeding** at 6 months
2^O **Survival** at 6 months
2^O Overall **HR-QOL** & Anti-Clot Therapy Scale (**ACTS**) at 3 and 6 months

Low Burden Study

Investigator Role
- Confirm eligibility
- Consent participant
- Prescribe anticoagulation therapy
- Report SAEs, only if they occur

CRA Role
- Register & randomize participant
- Administer baseline questionnaire
- Treatment Update Form at 2-weeks
- Medical Record Abstraction at 6-months

Participant Role
- Baseline questionnaire
- 3-month follow up questionnaire
- 6-month follow up questionnaire
- Drug diary

KEY ELIGIBILITY CRITERIA

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This trial (CANVAS | AFT 28) is funded by an award from the Patient-Centered Outcomes Research Institute (PCORI)

FUNDING SUPPORT

To learn more or to open this trial at your site, e-mail:

CANVAS@AllianceFoundationTrials.org

CONTACT US