CANCAS 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

- 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
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

Study Schema

R 1:1

Arm 1: Intervention (DOAC)
MD and patient choose:
- Rivaroxaban
- Apixaban
- Edoxaban
- Dabigatran

Arm 2: Usual Care (LMWH +/- Warfarin)
MD and patient choose:
- Dalteparin
- Enoxaparin
- Fondaparinux
- Warfarin

Study Outcomes
- Recurrent VTE
- Bleeding
- Survival

Enroll eligible participant within 30 days of DVT/PE diagnosis at any site where VTE is Symptomatic or Image-Detected

Current Accrual: 707
Study-wide Accrual Goal: 890
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

TREATMENT PLAN

Administer Protocol Treatment

Index VTE Diagnosis

Enroll/Randomize
(Within 30 days after index VTE diagnosis)

Begin Protocol Treatment
(Within 14 days after enrollment)

Off-Study
(6-months after study enrollment)

Off-study; physician and patient decide whether to continue anticoagulation therapy
**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 ≥ 18 Years**
  - Platelet ≥ 50,000/mm³ (≤ 7 days prior to enrollment)
  - CrCl ≥ 15 ml/min (≤ 7 days prior to enrollment)

**Exclusion**

- **Acute Leukemia**
- Received or scheduled to receive alloHSCT
- Scheduled to receive autoHSCT
- Significant **bleeding** (CTCAE grade 3 or 4)
- Ongoing **P-gp inhibitor** or **azole antifungals**
- **Pregnant/nursing**

**ELIGIBILITY CRITERIA**
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

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

**Participant Role**
- Baseline questionnaire
- 3-month follow up questionnaire
- 6-month follow up questionnaire
- Drug diaries

**CRA Role**
- Register & randomize participant
- Administer baseline questionnaire
- Treatment Update Form at 2 weeks
- Record episodes of bleeding and recurrent VTEs from medical record review at 6 months

**No Mandatory Appointments**
This trial (CANVAS | AFT 28) is funded by an award from the Patient-Centered Outcomes Research Institute (PCORI).

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

CANVAS@AllianceFoundationTrials.org

Deb Schrag (Study Co-Chair)
Deb_Schrag@dfci.Harvard.edu

Jean Connors (Study Co-Chair)
JConnors@partners.org

Eric Rodriguez (Study Coordinator)
EricN_Rodriguez@dfci.Harvard.edu