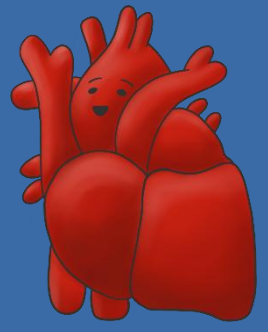

# DANCE Trial:

## *The Direct Oral ANticoagulation versus Vitamin K Antagonist after Cardiac SurgEry Trial*

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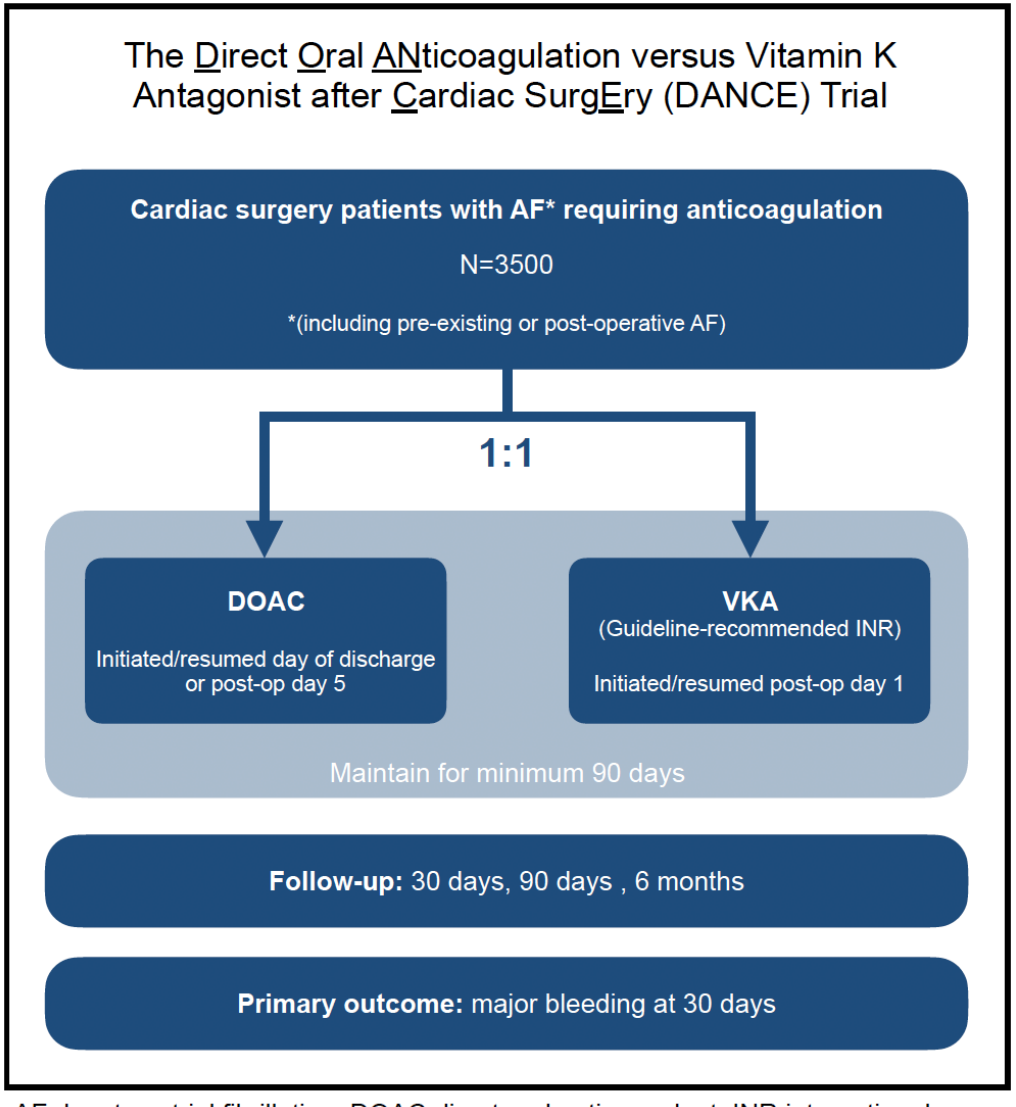
# Rationale

- Atrial fibrillation (AF) is associated with a higher risk of stroke
- Over 10% of patients going for cardiac surgery have a history of AF; 30-60% of patients will develop AF in the early post-operative period after cardiac surgery
- Oral anticoagulation (OAC) is used for thromboembolic prevention in AF
- In the early period after cardiac surgery, the balance of benefits and risks of OAC may differ and the most safe and effective OAC therapy is not certain
- Until 2009, **vitamin K antagonists (VKA)** were the only OAC agents available but their use is limited by a narrow therapeutic index to ensure appropriate levels anticoagulation, non-compliance and discontinuation
- **Direct oral anticoagulants (DOACs)** are a more convenient alternative compared to VKA
- The safety of DOACs vs. VKA in the early period after cardiac surgery remains uncertain

**DANCE**

# Trial Design & Intervention

| | |
|---|---|
| Study Design | Multi-centre, RCT comparing the safety of DOACs versus VKA in the early period (30 days) after cardiac surgery in patients with an indication for oral anticoagulation |
| Objectives | **Vanguard:** assess the feasibility of conducting a large RCT<br>**Full Trial:** Evaluate the safety & efficacy of DOACs vs VKAs after cardiac surgery in patients with AF requiring oral anticoagulation |
| Sample Size | **Vanguard:** n=800 \| **Full Trial:** n=3500 |
| Intervention | **Intervention Group:** will receive a DOAC at doses recommended for atrial fibrillation, adjusted for their renal function. Choice of DOAC will be at the discretion of the treating physician. DOAC may be resumed/initiated at the earliest on the day of discharge or on postoperative day 5, whichever occurs first.<br>**Control Group:** Patients will receive a VKA once daily; the individual dose will be titrated to achieve a guideline-recommended INR range. The first dose of VKA can be resumed/initiated as soon as postoperative day 1. |




AF denotes atrial fibrillation; DOAC direct oral anticoagulant; INR international normalized ratio; VKA vitamin K antagonist

# Trial Outcomes

Vanguard

## Feasibility Measures:

- average enrolment rate of 5 patients per centre per month
- proportion of participants that crossover OAC arms is < 5%
- ability to achieve follow-up at 30 days in ≥ 95% of enrolled patients

Full Trial

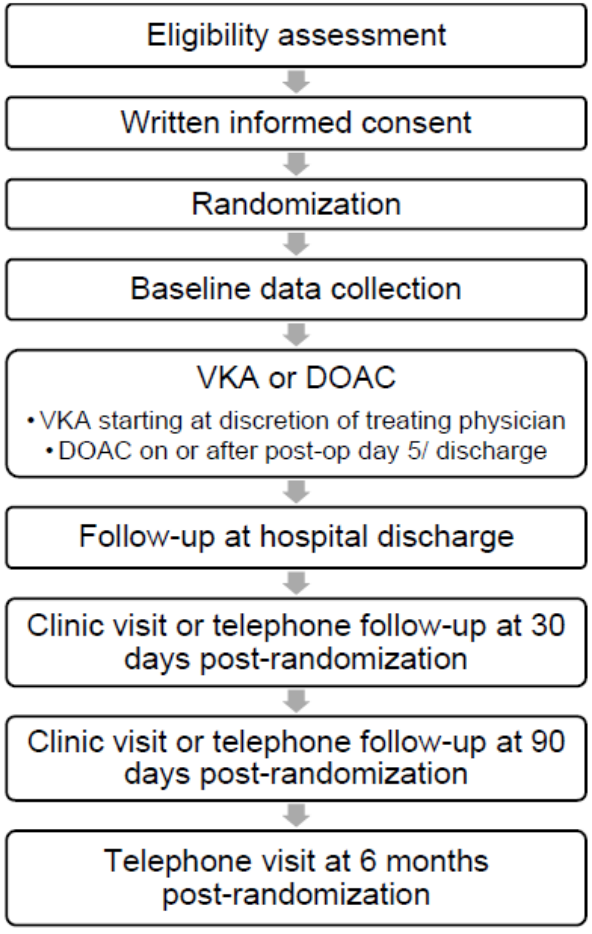
## Primary Outcomes Measures:

- Major bleeding at 30 days

## Secondary Outcomes:

- Most important: Composite of stroke and non-central nervous system systemic arterial embolism at 30 and 90 days.
- Major bleeding at 90 days; pleural effusion requiring drainage, pericardial effusion requiring drainage, systemic arterial embolism, ischemic stroke, deep vein thrombosis, pulmonary embolism, all-cause mortality, length of postoperative hospital stay at 30 and 90 days; all-cause mortality at 6 months.

# Trial Flow & Follow-up




DANCE

# SUNDANCE:

*SUbclinical valve thrombosis iN patients with surgical bioprosthetic valve replacement: An imaging substudy of the DANCE trial*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# Background Information

- Aortic and mitral valve replacements represent more than 90% of all surgical valve replacements
- Bioprosthetic valves do not require lifelong anticoagulation like mechanical valves, but they are susceptible to valve deterioration and failure
- **Subclinical valve thrombosis** occurs in 5-15% of patients at one year
  - May be related to increased risk of clinical valve thrombosis, stroke and thromboembolism, and reduced valve durability
- Anticoagulation reduces the incidence of subclinical valve thrombosis:
  - The effect of **direct oral anticoagulants (DOACs)** versus **vitamin K antagonists (VKAs)** on subclinical valve thrombosis has not been studied in a randomized control trial (RCT)

# SUNDANCE Design

**Study Design**

Substudy of DANCE

**Objectives**

**Vanguard:** assess the feasibility of conducting a large RCT
**Full Trial:** evaluate the incidence of subclinical valve thrombosis and any effect of DOACs vs VKAs in DANCE patients with a new bioprosthetic aortic and/or mitral valve

**Sample Size**

**Vanguard**: n=60 | **Full Trial**: n=910

**Intervention**

As in the overall DANCE trial

**Outcomes**

**Vanguard (feasibility):**

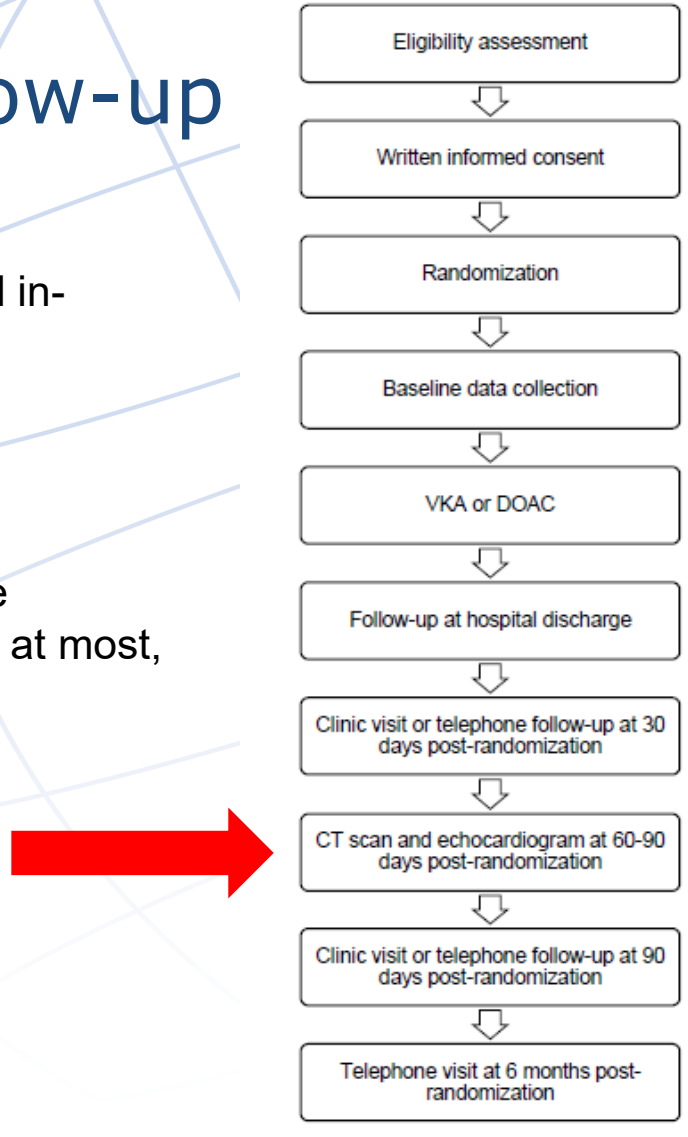
- Recruit ≥ 50% of bioprosthetic AVR and/or MVR patients enrolled in DANCE
- Complete 60 to 90-day CT scans and echos in ≥ 90% of patients
- At least “good” quality in ≥ 90% of CT scans

***Full trial:***

- Primary outcome: Incidence of subclinical valve thrombosis on CT scan performed 60-90 days

# SUNDANCE Flow & Follow-up

- In addition to standard DANCE trial follow-up, SUNDANCE participants will have one additional in-person follow-up visit at 60-90 days with:
  - Cardiac CT scan
  - Echocardiogram
- The cardiac CT scan and echocardiogram will be performed on the same day where possible, and at most, 14 days apart.

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