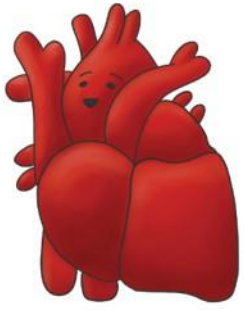

DANCE

The Direct Oral Anticoagulation versus Warfarin after Cardiac Surgery (DANCE) Trial

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Population Health Research Institute
HEALTH THROUGH KNOWLEDGE

Hamilton Health Sciences

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HEALTH SCIENCES

Background Information

- Atrial fibrillation (AF) is associated with higher risks of stroke and arises in 30-60% of patients in the early post-operative period after undergoing cardiac surgery
- Oral anticoagulation (OAC) therapy is the preferred method of thromboembolic prevention in patients however, 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, leading to non-compliance and discontinuation
- **Direct oral anticoagulants (DOACs)** have emerged as a more convenient alternative compared to VKA however no completed randomized control trial (RCT) has evaluated the safety of DOACs to VKA.

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	*Pilot:* assess the feasibility of conducting a large RCT *Full Trial:* evaluate the safety & efficacy of DOACs vs VKAs
Sample Size	Pilot: n=200 | Vanguard: n=400 | Full Trial: n=5900
Intervention	*Intervention Group*: will receive a DOAC daily starting at post-op day 5/ discharge and continues until day 30 post-rand *Control Group*: will receive a VKA once daily as early as post-op day 1 (at the discretion of the treating physicians) and continues until day 30 post-rand
Study Duration	30 days per patient

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Trial Outcomes

Pilot/ 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

Secondary Outcomes:

- Pleural effusion & pericardial effusion requiring drainage
- Systemic thromboembolism
- Ischemic stroke
- Deep vein thrombosis
- Pulmonary embolism
- Length of post-op stay

Tertiary Outcomes:

- Minor bleeding
- All bleeding (major + minor)
- Myocardial infarction
- Mortality
- Valve thrombosis
- Hemorrhagic stroke
- All stroke
- Thrombosis/ thromboembolism
- Quality of Life
- Aggregate costs for DOAC and VKA groups

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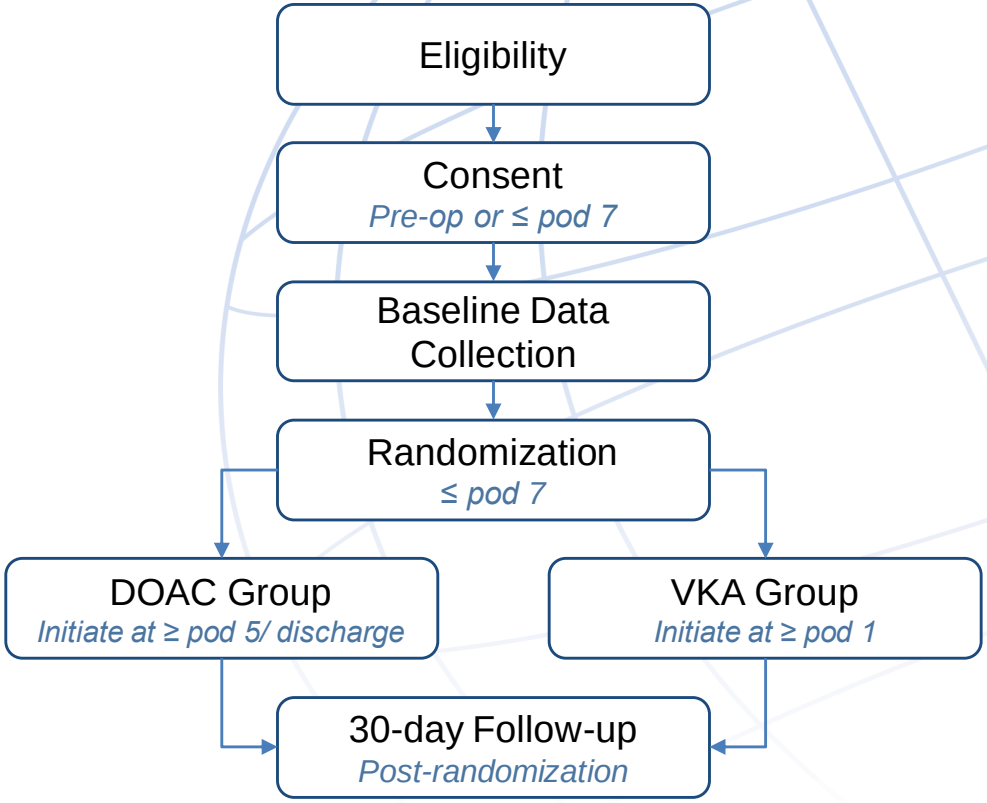
Trial Flow & Follow-up



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