

Pragmatic Randomized Clinical Trial of Early Dronedarone Versus Usual Care to **CHANGE** and Improve Outcomes in Persons With First-Detected Atrial Fibrillation (**CHANGE AFib**)

/ Summary

CHANGE AFib seeks to determine if early treatment with dronedarone improves cardiovascular and long-term outcomes in patients presenting to the hospital with first-detected AFib (diagnosed within the past 120 days). Enrolled patients will be randomly assigned (1:1) to:

- Trial intervention group: dronedarone 400 mg, twice daily, plus usual care
- Trial control group: usual care alone (per routine clinical practice)

/ Key study activities

Enrollment:

- Screen patients for eligibility
- Obtain participant informed consent
- Have participant sign a medical records release form
- Document participant's contact information

/ Study Coordinator

Name

Phone

Email

/ Inclusion criteria

- Age must be ≥ 21 years old
- First-detected AFib (diagnosed in the previous 120 days)
- Acute care encounter for evaluation or treatment of atrial fibrillation, within 120 days
- Electrocardiographic documentation of AFib
- Estimated life expectancy of ≥ 1 year
- Capable of giving signed informed consent by patient or legally authorized representative (LAR)

/ Exclusion criteria

- Patients with prior or planned treatment with rhythm control, either catheter ablation or chronic (>7 days) antiarrhythmic drug therapy
- Prior hospitalization for AFib (other than the qualifying event)
- Permanent AFib
- Planned cardiothoracic surgery
- New York Heart Association class III or IV heart failure (HF) or hospitalization for HF in the last 4 weeks
- Patients with reduced ejection fraction (LVEF $\leq 40\%$)
- Patients that are ineligible for oral anticoagulation, unless CHA₂DS₂-VASc is less than 3 in women or 2 in men
- Bradycardia with a resting heart rate < 50 bpm
- PR interval > 280 msec or 2nd-degree or 3rd-degree atrioventricular block without a permanent pacemaker/cardiac implanted electronic device
- Corrected QT interval ≥ 500 msec
- Pregnancy or breast feeding
- Severe hepatic impairment in the opinion of the investigator

/ Visit CHANGEAFIB.org for more information

