

PALLAS

Principal Investigator:

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Sub-Investigators:

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Sponsor:

Sanofi-Aventis US, Inc.

Study Purpose:

A randomized, double blind, placebo controlled, parallel group trial for assessing the clinical benefits of Dronedarone 400mg BID on top of standard therapy in patients with permanent atrial fibrillation and additional risk factors. Permanent Atrial fibrillation outcome Study using Dronedarone on top of standard therapy (PALLAS)

Objective:

The purpose of this protocol is to demonstrate the efficacy of Dronedarone in preventing major cardiovascular events (stroke, systemic arterial embolism, myocardial infarction or cardiovascular death) or unplanned cardiovascular hospitalization or death from any cause in patients with permanent atrial fibrillation and additional risk factors.

Inclusion Criteria:

- Patients in permanent atrial fibrillation defined by the presence of all of the following criteria:
 - Availability of one 12 lead ECG not more than 7 days prior to randomization, showing that the patient is in A-Fib or flutter.
 - Availability of documentation showing that the patient was in A Fib or Atrial flutter at least 6 months prior to randomization.
 - No evidence of sinus rhythm in the period between these two documentations of A Fib
 - Patient and physician decision to allow a Fib to continue without further efforts to restore sinus rhythm
- Patients aged 65 years or older with at least one of the following risk factors or combination of risk factors
 - Coronary artery disease, prior stroke, symptomatic heart failure, left ventricular ejection fraction less than or equal to 0.40, peripheral arterial occlusive disease, aged 75 years or older with both hypertension and diabetes mellitus

Written informed consent

Exclusion Criteria:

- Patients in paroxysmal AF

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- Persistent AF without a decision to allow atrial fibrillation to continue without further efforts to restore sinus rhythm
- AV node ablation, 3rd degree heart block, ICD, co-morbid conditions
- Previous participation in this or another clinical trial (60 days)
- Dronedarone Rx within previous 3 months
- Patients with heart failure of NYHA class IV or recent unstable NYHA class III
- Any exclusion related to Dronedarone (e.g., sustained daytime bradycardia < 50bpm, QTc interval > 500 msec, ect.)

Status:

Active enrollment

If you have any questions, please feel free to contact the coordinators, and they will be happy to answer any questions you have regarding this study.