Medtronic

FIRE AND ICE

Study Overview

Overview and Implications

FIRE AND ICE is the first prospective, randomized, multinational trial comparing effectiveness and safety of two atrial fibrillation ablation devices. This landmark study will compare the efficacy (defined as freedom from AF) and safety of isolation of the pulmonary veins between the Arctic Front® Cardiac CryoAblation Catheter system versus radiofrequency ablation using a THERMOCOOL® catheter, in combination with a CARTO™ 3D mapping system.

Atrial Fibrillation is one of the most common and undertreated cardiac arrythmias. The Arctic Front Cryoballoon and the THERMOCOOL catheter are the only two catheter ablation systems in the world that have both CE mark and FDA PMA approval for the treatment of drug refractory recurrent symptomatic PAF. Results of FIRE AND ICE will show definitively if the Arctic Front Cryoballoon is equal to the THERMOCOOL catheter in combination with a CARTO 3D mapping system for treatment of PAF in relation to effectiveness and safety at one year.

Trial Design

Study Population

- Up to 572 patients; with 1:1 randomization
- Main selection criteria:
  - Symptomatic paroxysmal atrial fibrillation with ≥ 2 episodes within the last three months and ≥ 1 episode documented
  - Documented treatment failure of ≥ 1 AAD

Design and Duration

- Investigator Initiated, Controlled, Prospective, Non-Inferiority, Randomized, Multicenter trial in 20 sites in Europe with a 12 months follow-up

Primary Outcome Parameter

- Time to first documented recurrence of atrial arrhythmias (a blanking period of three months will be maintained after the initial procedure)

Secondary Outcome Parameter

- Procedural data (total procedural duration, time of fluoroscopy, and duration of hospital stay), quality of life, sedation, flutter ablation, and survival time

Safety Analysis

- Primary safety outcome parameter: a composite of death (including cardiovascular death), stroke/transient ischemic attach (TIA) and serious adverse events of special interest (e.g., phrenic nerve palsy)
- Secondary safety outcome parameters: serious adverse events of all types and of each type separately and the components of the composite primary safety outcome parameter

Principal Investigator and Steering Committee

- Principal Investigator: Prof. Dr. Karl-Heinz Kuck, Hamburg, Germany
- Co-chair: Prof. Dr. Josep Brugada, Barcelona, Spain
- Steering Committee Members: Dr. Jean-Paul Albenque, Toulouse, France; Prof. Dr. Josep Brugada, Barcelona, Spain; Dr. David Wyn Davies, London, UK; Prof. Dr. Claudio Tondo, Milan, Italy; Prof. Dr. Karl-Heinz Kuck, Hamburg, Germany

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Inclusion Criteria:
- Up to 572 symptomatic PAF patients who failed ≥ 1 AF drugs

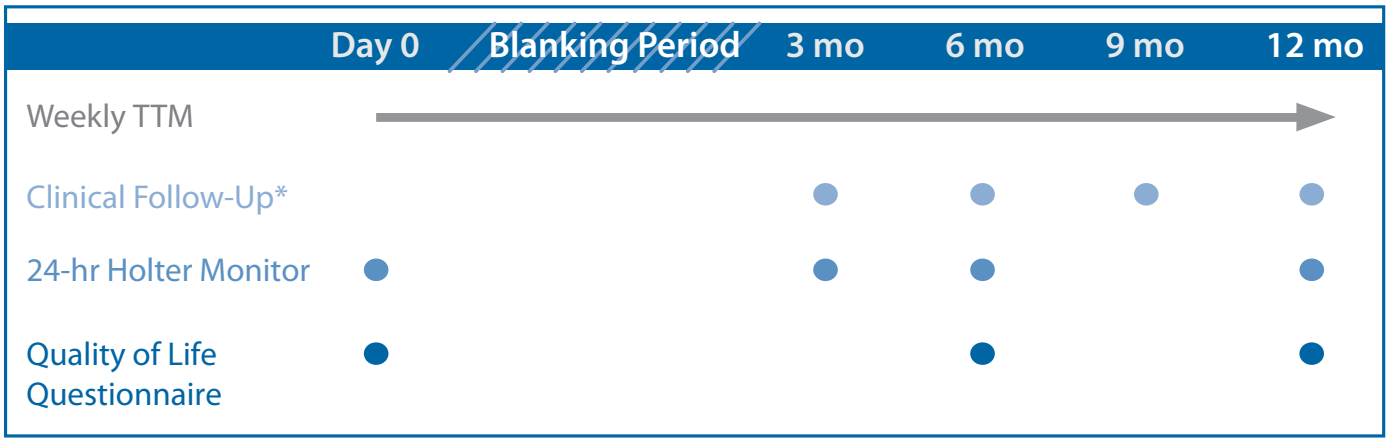
- 1:1 Randomization
- Cryoablation (Arctic Front Cryoballoon 23 or 28 mm) vs. Radiofrequency (THERMOCOOL catheter, in conjunction with CARTO® 3D mapping system)

Exclusion Criteria:
- LA diameter > 55 mm
- EF < 35%
- More than 2 cardioversions within 2 years
- Any previous LA ablation or surgery
- Recent cardiac surgery or PCI, MI

Cryoablation Group
N = 286

~20 sites in Europe

RF Ablation Group
N = 286



MRI/CT scan for symptomatic PV stenosis

* Follow-up call at 9 months

Additional Information
- International Standard Randomized Controlled Trials Number
- ClinicalTrials.gov Identifier: NCT01490814
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