Indication Extension for Medical Devices Using RWE from NESTcc Network Collaborators: Safety and Effectiveness of Cardiac Ablation of Persistent Atrial Fibrillation and Ischemic Ventricular Tachycardia Using Thermocool Catheters (NESTcc TC07 Phase 2)

First published: 23/02/2021

Last updated: 22/02/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS39629

Study ID

43262

DARWIN EU® study

No

Study countries

United States

Study description

The NESTcc Test Case 07 titled “The Feasibility of Using Real-World Data in the Evaluation of Cardiac Ablation Catheters,” was completed as of March 2020. This study is a follow-up study on the same medical devices and area of research as the initial feasibility study and would provide the opportunity to translate the advances and lessons learned in the feasibility study into an actual label expansion study that will be submitted to the FDA CDRH Office of Health Technology 2 (Electrophysiology). The specific aims are to use retrospective real-world data from the EHR systems at Mercy and Mayo Clinic to evaluate the safety and effectiveness of ablation for 1) persistent AF and 2) ischemic VT using ThermoCool catheters.

Study status

Ongoing

Research institutions and networks

Institutions

Mercy Healthcare System

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Institution

Mayo Clinic Rochester, MN

Networks

NESTcc

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Joseph Drozda

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2020

Actual: 01/07/2020

Study start date

Planned: 14/05/2021

Actual: 28/05/2021

Data analysis start date
Actual: 04/06/2021

Date of final study report
Planned: 31/08/2022

Sources of funding

- Other

More details on funding

Medical Device Innovation Consortium

Study protocol

NESTcc TC07 Phase 2 v7.3 Protocol.pdf (419.45 KB)

ThermoCool NEST Study Label Extension Protocol_final.pdf (639.66 KB)

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

Objective 1: demonstrate safety and effectiveness of ablation with ThermoCool ST catheters for treatment of persistent AF in real-world settings supporting label expansions of these catheters. Objective 2: demonstrate safety and effectiveness of ablation with ThermoCool STSF catheters for treatment of ischemic VT in real-world settings supporting label expansions of these catheters.

Study Design

Non-interventional study design

Cohort

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

1050

Study design details

Outcomes

Persistent AF: Primary safety endpoint is the cumulative incidence of a composite of primary adverse events (PAEs) occurring within 7 days of the initial and repeat ablation using ST catheter Ischemic VT: Primary safety endpoint is the cumulative incidence of a composite of cardiovascular-specific adverse events (CSAE) during and within 7 days post-ablation using STSF catheter, Persistent AF: Primary effectiveness endpoint is the incidence (rate and proportion) of a composite endpoint at 6 months and 1 year after specified index dates Ischemic VT: Primary effectiveness endpoint is the incidence (rate and proportion) of a composite endpoint at 6 months and 1 year after specified index dates

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Data analysis plan

Prior to the outcome analysis, the 2-stage propensity score strategy is used within each patient population separately within each health system to reduce confounding in the comparison of outcomes between groups. Demographic, clinical, procedural, and hospital and provider characteristics at baseline will be summarized descriptively for each group. Standard descriptive summaries for continuous variables will include the number of subjects with data, mean, and

standard deviation. The count and percentage will be generated for categorical variables. A head-to-head comparison using a non-inferiority design with a pre-specified non-inferiority margin will be conducted for a composite safety endpoint for persistent AF and a single arm design using a performance goal will be conducted for a composite safety endpoint for ischemic VT.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Electronic Health Records (EPIC) generated from Mercy and Mayo Health Systems

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No

Procedures

Procedure of results generation

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English (888.95 KB - PDF)

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