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Clinical evaluation of the DiamondTemp™ Ablation System for the treatment of ventricular tachycardia (a heart rhythm disorder caused by abnormal electrical signals in the ventricle of the heart)

Submission date 21/01/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/04/2024	**Overall study status** Completed	
Last Edited 19/02/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

Ventricular tachycardia is a type of arrhythmia that causes the heart to beat very fast. Ventricular tachycardia occurs in patients with weakened heart muscle or when scarring develops in the heart due to a myocardial infarction (heart attack). The scar or fibrosis can interfere with the normal electrical impulses of the heart, leading to a short-circuiting of the rhythm. A ventricular tachycardia can be treated with catheter ablation, a procedure that uses energy to make small scars in the heart tissue to prevent abnormal electrical signals from moving through the heart. The aim of this study is to evaluate the clinical results, safety and performance of the DiamondTemp™ Ablation System for the treatment of ventricular tachycardia.

Who can participate?

Patients aged over 18 years with ventricular tachycardia who are suitable candidates for catheter ablation and did not respond to anti-arrhythmic drug treatment

What does the study involve?

The ablation procedure will be performed according to routine hospital practice. The follow-up period is intended to align with standard practice and participants will be followed for 12 months after the procedure to collect safety and effectiveness data.

What are the possible benefits and risks of participating?

The Ablation System in this study is approved for use in Europe and the risks from taking part in this study are the same as someone undergoing routine ablation treatment under mapping /navigation guidance. It is not known whether participants will benefit from the treatment with this new ablation catheter system. Investigations such as this are performed in order to establish the relative risks and advantages of these treatments.

Where is the study run from?
Medtronic, Bakken Research Center B.V. (Netherlands)

When is the study starting and how long is it expected to run for?
March 2018 to January 2024

Who is funding the study?
Medtronic (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
308088

Central Portfolio Management System (CPMS)

51072

Protocol serial number
TP00923 - MDT20020

Study information

Scientific Title
A clinical evaluation of the DiamondTemp™ System TempeRAture Controlled Ablation for the treatment of Ventricular Tachycardia

Acronym
TRAC VT

Study objectives
The objective of this study is to assess the safety and performance of the DiamondTemp ™ Ablation System for the treatment of ventricular tachycardia (VT). The study is observational in nature and there is no pre-specified study hypothesis.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 26/07/2018, Ethics Committee for Research with Medicinal Products (CEIm, Hospital Universitario Ramón y Cajal, Madrid, None provided, Spain; +34 91 336 83 22; ceic.hrc@salud.madrid.org), ref: None provided

2. Approved 25/02/2022, West Midlands -South Birmingham Research Ethics Committee (Nottingham Health Research Authority, 2nd Floor, Equinox House, City link, Nottingham, NG2 4LA, United Kingdom; +44 (0)207 104 8000; southbirmingham.rec@hra.nhs.uk), ref: 22/WM/0017

3. Approved 23/05/2018, Ethics Committee of the Institute for Clinical and Experimental Medicine and Thomayer Hospital (IKEM, Videnska 800, Praha, 14059, Czech Republic; +420 (0) 236 055 012; eticka.komise@ftn.cz), ref: 24486/20 (A-18-03)

4. Approved 04/10/2018, Comité De Protection Des Personnes (CPP Ouest II, CHU Angers, None provided, France; +33 (0)2 41 35 52 15; cpp.ouest2@univ.angers.fr), ref: 2018/63 2018-A02425-50

5. Approved 03/10/2018, Ethics Committee of the IRCCS Istituto Europeo di Oncologia e Centro Cardiologico Monzino (European Oncology Institute and Monzino Cardiology Center Research Hospital) (None provided, Milan, None provided, Italy; +39 (0)2 57 489 848; comitato.etico@ieo.it), ref: R857/18-CCM 902

Primary study design
Observational

Study design
Prospective multi-center observational single-arm study

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Ventricular tachycardia

Interventions
The DiamondTemp Ablation Catheter used with the DiamondTemp RF Generator/Pump system is indicated for use in patients requiring cardiac electrophysiological mapping (stimulation and recording) and for cardiac ablation with monitoring of tissue temperature during ablation.

The DiamondTemp Ablation Catheter is a commercially available catheter that, when used with the DiamondTemp RF Generator and Irrigation Pump, is similar in functionality to existing open-irrigated electrophysiology (EP) ablation catheters and RF Generator/Pump Systems currently on the market.

Radiofrequency (RF) ablation will be performed using the DiamondTemp Ablation System. The ablation procedure will be performed according to routine hospital practice. The follow up period is intended to align with standard practice and subjects will be followed for 12 months post-procedure.

Intervention Type
Device

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
DiamondTemp Ablation System

Primary outcome(s)
The acute outcome is the successful ventricular tachycardia (VT) ablation (spontaneous and induced VT episodes), defined as the non-inducibility of VT, and the acute success rate determined as the percentage of acute successes out of all attempted DiamondTemp ablation procedures and index procedures, accompanied by a 95% exact Binomial confidence interval, measured using programmed electrical stimulation at the end of the ablation procedure.

The primary safety endpoint is considered successful if the subject is free from the composite of the following cardiovascular-specific SAEs within 30 days post-ablation that are adjudicated by the Clinical Events Committee (CEC) as (possibly) related to the DiamondTemp ablation procedure or system measured using patient medical records:
1. Cardiovascular-related death post-ablation
2. Cardiac tamponade/perforation
3. Bleeding complication
4. Myocardial infarction
5. Stroke or transient ischemic attack (TIA)
6. Thromboembolism
7. Pulmonary edema

The primary safety freedom rate will be estimated as the percentage of subjects free from the composite SAEs within 30 days post-ablation out of all subjects who attempt the DiamondTemp ablation procedure, along with a 95% exact Binomial confidence interval

Key secondary outcome(s)
The following secondary outcome measures are assessed using data recorded in the patient's medical records (scheduled study follow-up visits, unscheduled study follow-up visits, reported Adverse Events and ICD/CRT device information: a review of events from the device):
1. Chronic success is defined as no recurrence of VT through 6 months post-ablation procedure
2. Chronic safety is defined as freedom from cardiovascular-specific SAEs through 6-month post-ablation procedures that are adjudicated by the CEC as (possibly) related to the DiamondTemp ablation procedure or system. The list of cardiovascular-specific SAEs is equal to the list used for the primary safety objective.
3. Long-term safety is defined as freedom from cardiovascular-specific deaths through the 12-month post-ablation procedure that is adjudicated by the CEC as (possibly) related to the DiamondTemp ablation procedure or system

Completion date
01/01/2024

Eligibility

Key inclusion criteria
1. Above 18 years of age or minimum age as required by local law
2. Suitable candidate for catheter ablation
3. Subjects with symptomatic frequent monomorphic ventricular ectopy OR at least one documented episode of sustained VT meeting all the criteria below:
3.1. Episode occurring within previous 6 months
3.2. Episode must be monomorphic
3.3. Episode requiring external cardioversion or ICD anti-tachycardia pacing (ATP) or shocks
3.4. Structural heart disease with ischemic or non-ischemic dilated cardiomyopathy
4. Subject failed any anti-arrhythmic drug (AAD) regime unless contraindicated or not tolerated
5. Subject is willing and able to provide written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
38

Key exclusion criteria
1. Contraindication to catheter ablation
2. Ventricular tachycardia due to transient, reversible causes
3. Exclusively polymorphic VT
4. Electrolyte imbalance

5. Use of left ventricular assist device (LVAD) or circulatory assist devices
6. Stroke (<6 months)
7. Presence of a left atrial or ventricular thrombus
8. Severe cerebrovascular disease
9. Active gastrointestinal bleeding
10. Unstable angina
11. Renal failure (on dialysis or at risk of requiring dialysis)
12. Active infection or fever
13. Currently NYHA Functional Class IV heart failure
14. Left Ventricular Ejection Fraction (LVEF) <20%
15. Myocardial infarct or previous cardiac surgery (<3 months)
16. Prosthetic mitral or aortic valve
17. Mitral or aortic valvular disease requiring immediate surgical intervention
18. Active ischemia who are eligible for revascularization
19. Contraindication to heparin
20. Thrombocytopenia or coagulopathy
21. Uncontrolled diabetes needing therapy
22. Pregnancy or women of child-bearing potential
23. Unable to give informed consent
24. Unable to attend follow-up visits
25. Life expectancy <12 months based on medical history or the medical judgement of the investigator.
26. Enrollment in a concurrent clinical study that in the judgement of the investigator would impact study outcomes
27. Acute or chronic medical condition that in the judgment of the investigator would increase risk to the patient or deem the patient inappropriate to participate in the study

Date of first enrolment
04/06/2018

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
United Kingdom

England

Czech Republic

France

Italy

Spain

Study participating centre

Institute for Clinical and Experimental Medicine (IKEM)
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Czech Republic
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Study participating centre
Heart Rhythm Center, Monzino Cardiac Center University of Milan
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Study participating centre
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Sponsor information

Organisation
Medtronic (United States)

ROR
https://ror.org/00grd1h17

Organisation
Medtronic Bakken Research Cent

Funder(s)

Funder type
Industry

Funder Name
Medtronic

Alternative Name(s)
Medtronic Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because these data may be used for future product and therapy development.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/02/2025	19/02/2025	Yes	No