Clinical evaluation of the Gen2 irrigated ablation catheter for the treatment of cardiac arrhythmias

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON31563

Source
ToetsingOnline

Brief title
Gen2

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: St Jude Medical

Intervention

Keyword: Catheter ablation, Gen2, Irrigation

Outcome measures

Primary outcome

Acute Effectiveness (Technical Success) defined as:

• Achievement of pulmonary vein ostia isolation confirmed at least 30 minutes following the last RF ablation for pulmonary vein isolation with the Gen2 catheter

Chronic Effectiveness (Clinical Success) defined as:

• Freedom from paroxysmal or persistent atrial fibrillation at 6 months post-ablation in the absence of antiarrhythmic medication (Subjects maintained on a prevously ineffective dose of class I or class III antiarrhythmic medication will be evaluated for freedom from AF at 6 months post-ablation off antiarrhythmic medication)

• Freedom from SAE (Safety Success) defined as: Use of the Gen2 Irrigated Ablation Catheter does not result in unacceptable risk defined by specific serious adverse events identified in the clinical literature review listed .
If any Unanticipated Adverse Device Effects (UADEs) or 3 SAE*s from the CLINICAL LITERATURE IDENTIFIED SERIOUS ADVERSE EVENT LIST are recorded, the

study will be halted and deemed a failure.

Secondary outcome

None

Study description

Background summary

Catheter ablation is a standard treatment for cardiac arrhythmias. With catheter ablation, a small part of the heart that is responsible for the arrhythmia is heated and eliminated. This is done with radiofrequency current that is delivered via the distal electrode of an ablation catheter. The heating process can be monitored via a thermocouple in the ablation electrode. However, many ablations in left ventricle and left atrium require the use of an irrigated electrode that sprays saline during ablation to prevent blood clot formation. This irrigation cools not only the blood around the electrode, but also the electrode itself such that the electrode remains cool and the thermocouple inside it can not be used to monitor tissue heating. This may lead to ineffective applications that do not create large enough lesions, but it may also lead to excessive heating that may cause serious complications. Recently, Fred Wittkampf (UMC Utrecht, NL) and Hiroshi Nakagawa (Univ of Oklahoma, USA) have invented an irrigated electrode that uses thermally insulated irrigation channels. This allows monitoring of electrode temperature and thus tissue heating during ablation.

St. Jude Medical has developed the Gen2 Irrigated Ablation Catheter, an improved irrigated catheter with a 2.5mm tip which uses thermal insulated irrigation channels that allow the electrode to heat up during the ablation despite cooling of the surrounding blood. Small electrodes may produce comparable lesions to 4mm conventional catheters at lower power and the smaller electrode may additionally benefit the procedure by utilizing capabilities of discrete mapping. Lesions produced with a smaller catheter may be independent of tip orientation. These modifications have been extensively tested in bench and animal experiments to demonstrate safety and determine optimal recommended settings for electrode temperature and maximum radiofrequency power.

This study will confirm the effectiveness and safety of an improved irrigated ablation catheter due to its ability to monitor the effect of the ablation with greater precision.

Study objective

The purpose of this study is to confirm the Gen2 irrigated Ablation Catheter will perform as expected based upon the observed rates in the literature for effectiveness and safety for similar CE marked and commercially available irrigated and non-irrigated RF ablation catheters as documented in the Investigator Brochure.

Study design

This study is a prospective, non-randomised, confirmatory study of 103 subjects at up to 2 investigational sites in which outcomes the effectiveness and safety endpoints will be compared to previously reported results in the clinical literature.

Intervention

The intervention is cardiac catheterization using an ablation catheter that is slightly different from the catheter that is presently used in this patient population.

Study burden and risks

All candidates for the study will have the usual standard of care pre-cardiac catheterization exams and tests performed. The procedural intervention is the institution*s standard of care for cardiac catheterization using the investigational device (an irrigated ablation catheter that is slightly different from that which is presently used in these patients). Follow up visits will be per standard of care of the respective institutions. An additional phone call will be done at 4 weeks (+/- 7 days) to schedule the required tests and follow-up visit at 8 weeks post-procedure and to answer a few questions to assess post-procedure adverse events, atrial flutter or atrial fibrillation symptoms and antiarrhythmic medication. (See section 5.2, page 14-19 for details).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Be between eighteen and eighty years of age;
Be scheduled for an atrial fibrilation ablation procedure;
Be able to undergo contrast-enhanced MRI imaging;
Have a cardiac CT or MRI scan within a 6 months time window prior to the planned procedure ;
Be willing and able to sign the study specific consent form;
Be willing and able to fulfill study requirements (including study follow-up visits);
Have a negative pregnancy test for females in case of doubt about a possible pregnancy and
Have documented paroxysmal or persistent atrial fibrillation (by electrocardiogram (ECG); trans-telephonic monitor (TTM); Holter monitor or telemetry strip)

Exclusion criteria

Have evidence of or is currently receiving treatment for infection (local or systemic);
Have evidence of LA thrombus prior to procedure;
Be hypercoaguable (unable to tolerate heparin anticoagulation therapy) during the procedure;
Have history of embolic event(s). (e.g., cerebrovascular accident, pulmonary embolism, transient ischemic attack, etc.);
Have experienced a myocardial infarction <=3 months prior to the study procedure;
Have recent history (<=3 months) of cardiac surgery; including device implants (e.g. pacemaker, implantable cardiac defibrillator, etc.);
Have significant coronary heart disease or heart failure (i.e. unstable angina pectoris and/or

uncontrolled congestive heart failure resulting in NYHA Class III or IV) at the time of enrollment, except in cases where the NYHA Class III diagnosis is due to sustained AFL with rapid ventricular response;
Have history of any previous cardiac ablation for atrial fibrillation;
Have prosthetic heart valve or valvular heart disease requiring surgical intervention;
Have a pacemaker or ICD leads in or around the coronary sinus or coronary vasculature;
Be awaiting cardiac transplant or other cardiac surgery within the following 12 months;
Have significant pulmonary disease, or any other disease or malfunction of the lungs or respiratory system that produces chronic symptoms;
Have any condition for which the investigator feels it is unsafe for the subject to undergo an invasive EP catherization;
Have any condition for which the subject*s life expectancy is less than 12 months and
Be currently participating in another investigational study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-03-2008
Enrollment:	103
Type:	Anticipated

Medical products/devices used

Generic name:	Radiofrequency ablation catheter
Registration:	No

Ethics review

Approved WMO

Date:	30-09-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-11-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL18099.041.08