ACT Catheter System in Atrial Flutter, Advanced Cardiac Therapeutics: CE Trial Clinical Study

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This study is intended to assess the safety and performance of the ACT Catheter for ablation of right atrial isthmus dependent flutter, also known as typical atrial flutter.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON38247

Source
ToetsingOnline

Brief title
ACT Catheter System trial

Condition

- Cardiac arrhythmias

Synonym
abnormal heart rythm, atrial flutter

Research involving
Human

Sponsors and support

Primary sponsor: Advanced Cardiac Therapeutics, Inc
Source(s) of monetary or material Support: Advanced Cardiac Therapeutics;Inc

Intervention

Keyword: arrhythmias, Atrial flutter, microwave radiometry, radiofrequency ablation

Outcome measures

Primary outcome

Primary Objectives:

The primary objective of this study is to assess the safety and performance of the ACT Catheter for the diagnosis and treatment of atrial flutter.

The primary endpoints are defined by the following:

Safety: Acute Safety of the ACT Catheter will be evaluated by the absence of serious adverse events or serious adverse device effects during the time of the procedure and within seven (7) days afterwards.

Acute Ablation Performance: Ablation of atrial flutter with demonstration of block or isolation of signals confirmed after delivery of the ablation treatment.

Secondary outcome

Secondary Objectives:

The secondary objectives of this study are to assess the:

- manipulation and precise control of the device when used for mapping
- Chronic safety of the device.

The secondary endpoints are defined by the following:

Mapping and Manipulation Performance: Evaluation of performance is the ability of the physician to navigate to anatomical targets and the ability to create an electroanatomic map relevant to the procedure.

Chronic Safety Evaluation: Chronic safety evaluation at 30 days of the procedure as evidenced by adverse events and adverse device effects

Study description

Background summary

The ACT Catheter system consists of a manually steerable electrophysiology catheter, with an integrated, irrigated tip for the radiofrequency ablation of arrhythmias. Additionally the ACT Catheter system contains circuitry for measuring the temperature at depth of the ablated tissue using microwave radiometry and hooks up to an auxiliary device through a cable in order to display this temperature at depth to the user.

Study objective

This study is intended to assess the safety and performance of the ACT Catheter for ablation of right atrial isthmus dependent flutter, also known as typical atrial flutter.

Study design

The ACT Catheter System trial is a prospective, multi-center, single arm study, enrolling up to 30 subjects in Europe and New Zealand.
Patients with atrial flutter with indication for treatment with ablation technique are considered as potential patient for the trial.
Individual subjects will be studied during mapping and ablation with acute 7 day follow-up. It is anticipated that enrolment and safety follow-up will take approximately six weeks to complete. A chronic safety follow-up of 30 days will be evaluated.

Intervention

Prior to introducing the ACT Catheter into the patient, tranthoracic echocardiography will be used to evaluate the patient for structural heart

damage and pericardial effusion. The ACT Catheter will then be manually introduced and remotely navigated into the right and/or left atrium of the heart. As appropriate, the catheter will be remotely navigated to physician selected targets to create an electro-anatomical map and to ablate. With mapping and ablation complete, the ACT Catheter will be removed and tranthoracic echocardiography will be used to re-evaluate the patient for structural heart damage and pericardial effusion. Alternatively, if preferred, the physician can use a regulatory approved robotic system such as the Hansen Medical Inc Robotic System for navigating the ACT Catheter during the procedure.

Study burden and risks

Extensive in vitro bench and in vivo animal studies have been successfully performed with the ACT Catheter and verification testing for the catheter has been completed. The associated risks proposed in this study, are similar to risks posed by other interventional, electrophysiological cardiac procedures. The benefit to the subjects enrolled in this study is the potential for improved judgement by the clinician due to the additional information provided by the microwave radiometry functionality of the catheter.

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

1. Suitable candidate for catheter non-emergent intra-cardiac mapping and ablation.
2. Eighteen (18) to seventy five (75) years of age
3. Signed Informed Consent

Exclusion criteria

1. Intracardiac thrombus, tumor or other abnormality that precludes catheter introduction and placement
2. Severe cerebrovascular disease or history of cerebrovascular event (within 1 month)
3. Patients with severely impaired kidney function as measured by a Cockcroft-Gault Glomerular Filtration Rate (GFR) 3 with a GFR <= 29. This is calculated as follows for males:;GFR = (140 - age) x weight x .85 (for females)
PCr x 72;where age is specified in years, weight in kg, and PCr is Serum Creatinine in Mg /dL Female GFR is reduced by 15% of the above calculated value for males.
4. Active gastrointestinal bleeding
5. Active infection or fever (> 100.5 F/38 C)
6. Sepsis
7. Cardiac surgery within the past two months
8. Short life expectancy (< 1 yrs) due to other illnesses, such as cancer or pulmonary, hepatic, or renal disease
9. Significant anemia (hemoglobin < 8.0 mg / dL)
10. Severe uncontrolled systemic hypertension (systolic press. > 240 mm Hg within the last 30 days)
11. Documented anaphylaxis during previous exposure to angiographic contrast media
12. Uncontrolled congestive heart failure (NYHA Class III or IV)
13. Unstable angina or acute myocardial infarction within the past three months
14. Bleeding, clotting disorders, or known thrombosis
15. Peripheral vascular disease
16. Uncontrolled diabetes
17. Women who are pregnant and not willing to use contraception for the duration of the study, 30 days
18. Active participation in another investigational protocol
19. Unable or unwilling to take anti-coagulants
20. Unwilling or unable to comply with any protocol or follow up requirements

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-03-2011
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	ACT Catheter system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-10-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-05-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL33139.100.10