Clinical Investigation of the VytronUS Ablation System for Treatment of Symptomatic Drug-refractory Paroxysmal Atrial Fibrillation

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Safety: To provide scientific evidence that use of the VAS is safe as measured by the incidence of early-onset serious adverse events (SAEs).Effectiveness: To provide scientific evidence that use of the VAS provides an effective treatment for...

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

Summary

ID

NL-OMON46588

Source
ToetsingOnline

Brief title
VITAL

Condition

- Cardiac arrhythmias

Synonym
Cardiac arrhythmia, recurrent paroxysmal atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: VytronUS, Inc.

Source(s) of monetary or material Support: industry: VytronUS;Inc.

Intervention

Keyword: Ablation, Atrial Fibrillation, ultrasound, VytronUS Ablation System

Outcome measures

Primary outcome

Safety: The primary safety endpoint will report the incidence of early onset primary serious adverse events (PSAEs) occurring within 7 days of the index procedure or hospital discharge, whichever is later, and diagnosed at any time during the follow up period.

Effectiveness: The primary effectiveness endpoint of the study will report the rate of treatment success as defined by both:

* Acute procedural success - electrical isolation of all 4 pulmonary veins (PVs), or in the event of a common PV, the clinical equivalent of all PVs by the end of index procedure using the VAS.

* Chronic success - acute procedural success and freedom from re-treatment with ablation, recurrence of symptomatic atrial fibrillation (AF), atrial flutter (AFL), and atrial tachycardia (AT) lasting longer than 30 seconds through 9 months of follow-up after a 3 month blanking period. Use of a previously prescribed Class I or III antiarrhythmic drug (AAD) at the same or lower dose, or re-ablation during the blanking period with VAS does not constitute a treatment failure.

Secondary outcome

Safety: The secondary safety endpoint will report the incidence of all serious adverse events (SAEs) during the 12 month follow up period.

Effectiveness: The secondary effectiveness endpoint will report:

* Change in Quality of Life from baseline assessed by 1) European Heart Rhythm

Association (EHRA) score of AF-related symptoms, and 2) SF-36 Health Survey

* Patients free from atrial arrhythmia on Holter at 12 months

Study description

Background summary

In summary, extensive bench and pre-clinical testing have defined safe parameters for
operation. Results from the VytronUS* VLIC-USA and VALUE studies demonstrate that the VAS
performs in a satisfactory manner. The VAS may be a valuable addition to existing technology
available to treat PAF and should be studied in a larger clinical trial.

Study objective

Safety: To provide scientific evidence that use of the VAS is safe as measured by the incidence of early-onset serious adverse events (SAEs).
Effectiveness: To provide scientific evidence that use of the VAS provides an effective treatment for symptomatic paroxysmal atrial fibrillation (PAF).

Study design

VITAL is a prospective, single arm, multicenter, interventional study to evaluate the safety and effectiveness of the VytronUS Ablation System (VAS) for the treatment of symptomatic paroxysmal atrial fibrillation (PAF) using low intensity collimated ultrasound (LICU) for imaging and ablation.
Patients undergoing elective catheter ablation for symptomatic PAF who are refractory or intolerant to at least one antiarrhythmic drug (Class I-IV) will be screened for enrollment. Patients who meet the study entry criteria and sign the patient informed consent form will be enrolled and treated consistent with the 2012 Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA)/European Cardiac Arrhythmia Society (ECAS) Expert Consensus Statement on Catheter and Surgical Ablation for Atrial Fibrillation.
Eligible patients will receive treatment with the VAS including ultrasound imaging of the left atrium and cardiac ablation to electrically isolate the pulmonary veins.
After the index procedure, patients will be followed for a total of 12 months

for chronic effectiveness assessment, beginning with a 3-month blanking period and ending with a 9-month effectiveness assessment period. Patients will be evaluated at pre discharge, at 7 days, at 3, 6 and 12 months post index procedure.
Up to 100 patients will be enrolled at up to 10 sites in Europe (EU) and in the United States (US).

Intervention

Patients will receive a catheter-based cardiac ultrasound anatomical mapping and ablation
procedure using the VAS.

Study burden and risks

The planned ablation procedure is associated with certain risks that exist for all ablation procedures. These risks include reactions to medication and/or drugs that are administered during anesthesia, thrombosis (blood clot), blood loss, cardiovascular (heart) problems, fever, infection and in rare cases the patient may even die. New complications may arise in any treatment procedure, the type and severity of which cannot be foreseen at present. For those procedures where the physician applies sedation or anesthesia, the standard risks of anesthesia also exist.

Complications associated with the use of the study device may be related to the device or the procedure have been evaluated in published research and may include, but are not limited to the risks listed below:

* Injury to the heart muscle or tearing of the heart muscle with subsequent bleeding into the pericardium (heart sac) surrounding the heart. The chance of this complication causing a drop in blood pressure and additional treatment has been reported in the literature to be from 0.2% - 5%.
* Growth of scar tissue inside the pulmonary veins (large blood vessel that carries blood from the lungs to the left upper chamber of the heart) with the risk of narrowing or blockage of the pulmonary veins. The chance of this complication is less than 1%.
* Development of blood clots and the movement of blood clots, during or after the procedure. The patient is given an anti-blood-clotting medication to help stop the blood clots from developing. The chance of this complication is from 0% - 2%.
* Introduction of air into the vessels which may lead to heart attacks or strokes. The chance of this complication is less than 1%.
* Permanent injury to the phrenic nerve which is responsible for control of breathing. Damage to this nerve causes breathing difficulties especially during exercise. The chance of this complication is from 0% - 0.4%.
* Damage to the esophagus, the tube that carries food, liquids and saliva from

your mouth to the stomach called a fistula between the left upper chamber of the heart and the esophagus. The chance of this complication is from 0.2% - 0.11%.
* Bleeding after the procedure at the point where the catheter was put into the body. The chance of this complication is from 0.2% - 1.5%.
* Injury from X-rays. The chance of this complication is less than 0.1%.
* Occlusion of a blood vessel in the brain due to air or a blood clot that does not cause any immediate symptoms but may impair cognitive ability in the future. The chance of this complication is from 2% - 15%.
* Death. The chance of this complication is from less than 0.1% - 0.4%.
* Injury to the vagal nerve causing impairment of normal gastric function and nausea, vomiting or pain. The chance of this complication is from 0% - 17%.
* Mechanical damage to the mitral valve caused by a circular mapping catheter normally used as part of the procedure. The chance of this complication is less than 0.1%.
* Inflammation of the epicardial (exterior) surface of the heart causing chest pain. Minor inflammation is extremely common after an ablation procedure. Some patients have more severe symptoms. The chance of this complication is from 0% - 50%.
* Reduced left atrial function due to formation of scar tissue in the heart. The chance of this complication is less than 1.5%.

It is possible that your physician may administer a shock using patches on your chest to terminate a very fast heart rhythm. If a shock is delivered from the patches, this could cause mild skin burns or irritation.
During the procedure, you will be exposed to radiation when your doctor has to make images of your heart during the placement of the catheters into their correct position. The amount of radiation to the skin is about 1/60th of the amount of radiation that could cause skin injury. The effective radiation dose to your body is on the order of 1200 mrem. For comparison, a radiation worker can receive a maximum amount of radiation exposure of 5000 mrem in a year*s time and the level of radiation received from natural background in a year in many areas of the world is around 300mrem.
If a CT scan is performed, an additional 2000 mrem radiation dose may be received.
If you undergo a MRI scan (during which you will not be exposed to x-rays), there are different potential risks or discomforts associated with this:
* Temporary hearing loss due to the loud noise
* Stiffness due to lack of movement
* Mild lightheadedness
* Sweating due to the heat from the MRI machine
* Warm body sensation after the exam is done
* Feelings of claustrophobia (fear of enclosed spaces)
Patients who have had an ablation procedure are routinely treated with anticoagulant medications for a number of months and you will need to continue

this medication for at least 5 months. There is an increased risk of bleeding while taking these medications and you should tell your doctor if you have any abnormal bleeding.
You must not participate in this study if you are pregnant or are trying to become pregnant as there might be unknown risks you or for the unborn child.
There is a possibility that your doctor may have to perform an ablation again in the future if the atrial fibrillation returns. This is quite common for patients with your condition. Although the sponsor and your medical team make every effort to reduce risks, there may also be unanticipated risks related to the participation in this study.

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. Age between 18 and 75 years
2. History of symptomatic recurrent paroxysmal atrial fibrillation (PAF) in the prior year, defined by:
a. Two or more symptomatic AF episodes lasting greater than 30 seconds duration that self-terminate and lasting no more than 7 continuous days. An episode of AF * 48 hours duration terminated with electrical or pharmacologic cardioversion counts as a paroxysmal atrial fibrillation episode.
b. At least one episode of paroxysmal atrial fibrillation (PAF) documented on 12-lead ECG, event monitor, or telemetry monitor in the prior year
3. Paroxysmal atrial fibrillation refractory to at least one Beta Blocker, Calcium Channel Blocker, or Class I or Class III anti-arrhythmic drug (AAD).
4. Subject is indicated for a pulmonary vein ablation according to society guidelines or investigational site practice.
5. Subject is able and willing to give informed consent.
6. Willingness, ability, and commitment to participate in baseline and follow-up evaluations for the full duration of the study

Exclusion criteria

1. Prior LA ablation or surgery
2. Persistent, longstanding persistent, or permanent AF
3. AF secondary to electrolyte imbalance, thyroid disease or reversible or non-cardiac cause
4. NYHA Class III or IV congestive heart failure
5. Rheumatic heart disease
6. Atrial myxoma
7. LVEF <40% measured by acceptable cardiac testing (e.g. TTE, TEE)
8. Anteroposterior LA diameter >5.5cm or <3.5cm by TTE, CT or MRI
9. Presence of intracardiac thrombus (including a known history of thrombus) within 30 days prior to the index ablation procedure
10. Presence of pulmonary vein stent(s)
11. Presence of pre-existing pulmonary narrowing or pulmonary vein stenosis greater than 70%
12. Presence of pre-existing pericardial effusion
13. Previous mitral valve repair or prosthesis
14. Bleeding diathesis or contraindication to anticoagulation therapy
15. Known blood clotting abnormalities (e.g., genetic)
16. MI, PCI, or cardiac surgery within 90 days prior to the index ablation procedure
17. Previous CVA, TIA, or PE within 3 months prior to the index procedure
18. Structural heart defect that, in the investigator*s opinion, prevents catheter access or increases risk of ablation procedure
19. Pacemaker, ICD, or CRT with pacing leads implanted within 3 months prior to the index ablation procedure

20. Subjects in whom PVI is contraindicated based on an intra-procedural finding such as AVRT/AVNRT will be excluded from the primary endpoint analyses and followed for safety only
21. Active systemic infection
22. Subject contraindicated for both contrast MRI and CT
23. Life expectancy less than 360 days in physician*s opinion
24. Participation in a drug or device study that could conflict with this study
25. Women known to be pregnant or breastfeeding or of childbearing potential unless on satisfactory contraceptive routine
26. Exclusion as per local laws

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2018
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	VytronUS Ablation System (VAS)
Registration:	No

Ethics review

Approved WMO

Date:	05-06-2018
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-07-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL62214.078.17