Phased RF Evaluation of ACute Pulmonary Vein ISolation In ParOxysmal AF with New GENius UI and PVAC® Gold

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The purpose of this clinical study is to evaluate asymptomatic cerebral embolic (ACE) in subjects with symptomatic paroxysmal atrial fibrillation (AF) undergoing ablation with the Pulmonary Vein Ablation CAtheter GOLD (PVAC GOLD).(See also p. 13 of...

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

Summary

ID

NL-OMON39982

Source
ToetsingOnline

Brief title
PRECISION GOLD

Condition

- Cardiac arrhythmias

Synonym
heart rhythm disorders - atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.
Source(s) of monetary or material Support: Medtronic Inc.,Medtronic, Inc.

Intervention

Keyword: Ablation procedure, Atrial Fibrillation, Evaluation asymptomatic cerebral embolic lesions

Outcome measures

Primary outcome

Report rate of ACE (number of subjects presenting with post-procedural

asymptomatic cerebral embolic lesions as determined by MRI)

Secondary outcome

The Secondary study objectives are:

- Characterize Acute procedural success

--> Acute procedural success will be defined as: only PVAC GOLD catheters(s)

used to achieve pulmonary vein isolation AND all accessible

pulmonary veins were isolated (entrance block) AND sinus rhythm is

restored at the end of the ablation procedure (with or without

cardioversion)

- Report procedure and device related serious adverse event rate

--> Summarize all procedure and/or device related serious adverse events

using PVAC GOLD within 30 days of an ablation procedure.

The ancillary study objectives are:

- Report PVAC GOLD procedure times

Report procedure times including total time, total fluoroscopy time, time spent

in Electrophysiology (EP) lab/Operating Room (OR), LA dwell time, total energy

delivery time.

- Report procedure details

• Number of energy applications per vein

• Energy modes used

• Electrodes turned off/on

- Report cumulative RF energy delivered

- Summarize results of MMSE

- Summarize adverse events

Study description

Background summary

Phased RF ablation of the pulmonary vein is an approved treatment for paroxysmal, persistent, and permanent atrial fibrillation in Europe. The Medtronic CE-Marked PVAC is a multi-electrode catheter used to map, ablate, and verify isolation of the PVs. In combination with the GENius generator, this phased array system can deliver radiofrequency (RF) energy to isolate PVs via creation of circumferential lesions. PVAC GOLD is a line extension of PVAC with three design modifications. Pre-clinical studies have demonstrated that the design changes do not affect the safety and efficacy. The study was designed to characterize the ACE (asymptomatic cerebral embolism) rate using PVAC GOLD. (See also page p. 12 and p. 13 of the CIP: 2. Background and Justification)

Study objective

The purpose of this clinical study is to evaluate asymptomatic cerebral embolic (ACE) in subjects with symptomatic paroxysmal atrial fibrillation (AF) undergoing ablation with the Pulmonary Vein Ablation CAtheter GOLD (PVAC GOLD).

(See also p. 13 of the CIP: 1.1: Study Purpose)

Study design

PRECISION GOLD is a, prospective multi-center, single arm, unblinded, interventional postmarket clinical study designed to evaluate PVAC GOLD with regard to acute subject outcomes including, evaluation of the post-procedural ACE rate, acute procedural success and assessment of procedure and/or device related serious adverse events.

Intervention

The following information is required to be collected at the ablation procedure or within specified timeframe prior to the ablation procedure:
• MRI scan (FLAIR and diffusion weighted) within 48 hours prior to procedure
• Concomitant medications and anticoagulation use
• TEE to rule out left atrial thrombus (within 48 hours of procedure)
• INR (required to be >= 2 on the day of procedure; if between 1.8 and 2.0, subject required to be treated with heparin or low molecular weight heparin within 4 hours post-procedure until INR is >= 2)

Procedure preparation
• Inject heparin bolus immediately before and/or immediately following transseptal puncture.
• Administer heparin bolus and start continuous heparin infusion to maintain ACT >=350 seconds throughout the procedure.
• Check ACT levels until target level of 350 seconds is reached.
• Do not ablate with the PVAC GOLD catheter unless ACT levels are at or above 350 seconds.
• Continue to measure ACT every 15-30 minutes throughout the procedure, until PVAC GOLD is removed from the body.

PVAC GOLD catheter introduction
• Follow catheter introduction and use instructions described in the instructions for use
• It is recommended to capture the spiral array in the capture device while submerged in a saline and/or heparinized saline bath
• It is recommended to vigilantly flush and/or aspirate the sheath to exclude air ingress.

PVAC GOLD pulmonary vein ablation
• Follow instructions described in the catheter instructions for use and generator operator manual
• Map for pulmonary vein potentials
• Verify isolation of the pulmonary veins after 30 minutes

Study burden and risks

There are possible risks and inconveniences in connection with the use of the device PVAC® GOLD, followed procedures and with the participation in the study. Since the procedure is not an experimental one, the risks and inconveniences associated with the procedure are the same as if the patient were not in this study.
The PVAC GOLD is inserted through a minimally invasive procedure. These side effects may occur which are known for such procedures. For instance, complications due to anesthesia, infection, bleeding, worsening of existing symptoms and complications in the healing can occur. Moreover, some unexpected side effects.

Hereunder are listed the possible risks or side effects that can occur during and after an MRI. These potential risks associated with the MRI are the same as those for any patient who undergoes an MRI:
• 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)

Contacts

Public
Medtronic B.V.

8200 Coral Sea Street N NE
Mounds View, MN 55112
US
Scientific
Medtronic B.V.

8200 Coral Sea Street N NE
Mounds View, MN 55112
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subject has Symptomatic paroxysmal AF defined as :
- Episodes of AF
- >=2 recurrent AF episodes that self-terminate, lasting no more than 7 continuous days or
- episodes of AF <= 48 hours duration terminated with electrical or pharmacologic cardioversion
counts as a PAF episode
- Electrocardiographically documentation of one or more events with PAF (ECG, event recordings,
pacemaker strips or monitor rhythm strips) within the past year
- AF symptoms defined as the manifestation of any of the following: palpitations, fatigue, exertional dyspnea, effort intolerance;Subject is on a Vitamin K antagonist (i.e. Warfarin/Coumadin)
Subject between 18 and 70 years old
Subject is indicated for a pulmonary vein ablation
Subject is able and willing to give informed consent
Willingness, ability and commitment to participate in baseline and follow-up evaluations for the full length of the study.

Exclusion criteria

Subject has persistent or permanent AF
Subject has had a prior left atrial ablation
Subject has a intracardiac thrombus
Subject is contraindicated for Vitamin K antagonist (i.e. Warfarin/Coumadin)
Subject is prescribed to direct thrombin or factor inhibitors (i.e. Dabigatran, Rivaroxaban)
Subject prescribed any investigational drug that may confound the study results
Subject has a cardiac valve prosthesis
Subject has a significant congenital heart defect corrected or not (including atrial septal defects or pulmonary vein abnormalities but not including minor PFO)
Subject has pulmonary vein stents

Subject has any pre-existing pulmonary vein stenosis
Subject has had a cerebral ischemic event (strokes or TIAs) which occurred during the 6 month interval preceding the Consent Date
Subject is a woman known to be pregnant
Participation in any other cardiovascular clinical study
Subject contraindicated for MRI
Subject has active sepsis
Subject has blood clotting abnormalities (genetic)
Subject has left atrial myxoma
Subject has a venous filtering device (Greenfield filter)
Subject has had an invasive cardiac procedure in the past 90 days

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):	28-01-2014
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	PVAC GOLD: Pulmonary Vein Ablation Catheter System GOLD
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-04-2013

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-11-2013
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	NL42569.100.12