Ventricular tachyarrhythmia detection by Implantable Loop Recording in Patients with Heart Failure and Preserved Ejection Fraction

Published: 16-06-2014
Last updated: 24-04-2024

To study the incidence of 'sustained' ventricular tachyarrhythmias in patients with HFpEF.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON47257

Source
ToetsingOnline

Brief title
VIP-HF Registry

Condition

- Heart failures

Synonym
Diastolic heart failure; heart failure with preserved ejection fraction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Heart failure with preserved ejection fraction (HFpEF), Implantable loop recorder, Safety, Ventricular tachyarrhythmia

Outcome measures

Primary outcome

The primary objective (efficacy) is to assess the incidence of sustained

ventricular tachyarrhythmias.

Secondary outcome

1. To assess the incidence of all cause mortality, cardiovascular mortality,

and sudden cardiac death

2. To assess the incidence of ICD-related complications

3. To assess the incidence of non-sustained tachyarrhythmias or slow

ventricular arrhythmias

4. To assess the incidence and burden of AF

5. To assess biomarkers (including echocardiography, 6 minute walk test, ECG

and other arrhythmogenic markers and blood biomarkers) for adequate ICD

therapies

6. To assess biomarkers (including echocardiography, 6 minute walk test, ECG

and other arrhythmogenic markers and blood biomarkers) for inadequate ICD

therapies

7. To assess biomarkers (including echocardiography, 6 minute walk test, ECG

and other arrhythmogenic markers and blood biomarkers) for development of

atrial or ventricular arrhythmias

8. To assess biomarkers (including echocardiography, 6 minute walk test, ECG

and other arrhythmogenic markers and blood biomarkers) for development of HF hospitalizations and mortality

9. To assess the relation between cardiac amyloid deposition and other biomarkers (including ECG, 6 minute walk test, Holter, echocardiography, CMR and blood biomarkers) and incidence of sustained ventricular tachyarrhythmias, incidence of atrial fibrillation, and development of HF hospitalizations, sudden death, arrhythmic death, and all-cause mortality

Study description

Background summary

Heart failure with preserved ejection fraction (HFpEF) is a large medical problem, for which no drug or device has a recommendation in current HF guidelines. Sudden cardiac death is probably the most common cause of death in HFpEF patients. Use of an Implantable Cardioverter Defibrillator (ICD) may be useful in some patients with HFpEF. The VIP-HF registry aims to evualate the possible utility of ICD therapy in HFpEF.

Study objective

To study the incidence of 'sustained' ventricular tachyarrhythmias in patients with HFpEF.

Study design

Multicenter, prospective, non-randomized, intervention study.

Intervention

ICD implantation.

Study burden and risks

The present study may render important insights into the incidence of sustained ventricular tachyarrhythmias in patients with HFpEF. Present observational study may help to increase the knowledge on the incidence of life-threatening

ventricular tachyarrhythmias and therefore provide insight into sudden cardiac death in patients with HFpEF. Eventually, this may lead to improved risk stratification, therapeutic choices (ICD implant) and hence patient-tailored therapy. At present no drug or device therapy has been proven beneficial in patients with HFpEF. Currently, the ESC guidelines do not recommend ICD implantation in the present study population.

In all patients an ILR will be implanted, which is associated with some peri-procedural risks: infection and bleeding (risk < 1%). These complications are rarely life-threatening. Patients will be informed in detail about the risks. Blood sampling (24.5 cc each) occurs during vena punctures performed for usual care, however, present study requires 3 additional vena punctures (inclusion, after 12 months and 24 months of follow up). Risks of a vena puncture are very slight and include excessive bleeding, fainting or feeling light-headed, hematoma, local infection. Obtaining a blood sample from some people may be more difficult than from others.

The usage of positron emitting isotopes in the 99m technetium scan translates to an exposure to ionizing radiation. Because of the potential hazards of radiation exposure, guidelines for the exposure of healthy volunteers are laid down in *Besluit stralingsbescherming, artikel 60, staatblad 2001, 397* in accordance with the guidelines of the International Commission on Radiological Protection (ICRP). The radiation dose of 99mTc-HDP is 0.0057 mSv/MBq for adults. Patients will receive a total dose of 700 MBq IV, which translates to a total radiation dose of ± 3.99 mSv for the 99mTc-HDP scan. The radiation of a low dose CT is approximately 1.5 mSv, which totals to a dose of 5.49 mSv combined with the 99mTc-HDP scan. This complies with category IIb, ICRP 62. The radation dose is calculated by our local clinical physicist. There are no other study-related procedures required.

There are no other study-related procedures required. VIP-HF registry patients will be implanted with a cardiac monitor. The total incidence of peri-procedural complications is < 1% in experienced centers.

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

Clinical criteria:
1. Age >18 years
2. Written informed consent
3. HF with moderate to severe symptoms NYHA II or III
4. Hospitalization or emergency room visit for HF or symptom relief with diuretics within 12 months
5. Sinus rhythm or AF with adequate rate control (exercise test: maximum heart rate <160 bpm) ;Echocardiographic criteria:
1. LVEF >40%
2. Left atrial size (volume *34 mL/m2 or LA parasternal diameter *45 or left ventricular hypertrophy (septal thickness or posterior wall thickness *11 mm) of left ventricular diastolic dysfunction (E/e* *13 or mean e* septal and lateral wall <9 cm/s).;Biomarker criteria:
1. BNP >75ng/L or NT-pro-BNP>300ng/L if sinus rhythm
2. BNP >225ng/L or NT-pro-BNP>900ng/L if atrial fibrillation

Exclusion criteria

1. Patients unwilling or unable to sign informed consent
2. Patients with a pacemaker or ICD
3. Indication for ICD therapy according to the European Society of Cardiology (ESC) guidelines
4. Life expectancy of less than one year
5. Significant coronary artery disease or myocardial infarction < 3 months
6. Complex congenital heart disease

7. Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-12-2014
Enrollment:	250
Type:	Actual

Medical products/devices used

Generic name:	Implantable Loop Recorder (ILR)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-06-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Not approved

Date:	01-05-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	16-09-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-04-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-10-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-04-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-07-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT01989299
CCMO	NL47026.042.13