A Clinical Evaluation of ST Changes in a group of Patients having ventricular arrhythmias

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The purpose of this investigation is to determine the prevalence of device-recorded ST segment changes occurring before appropriate ICD therapies (ATP or Shock) and to define their temporal relationship to ventricular arrhythmias.

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

Summary

ID

NL-OMON39693

Source
ToetsingOnline

Brief title
Insight

Condition

- Cardiac arrhythmias

Synonym
ECG shifts, Ventricular arrhythmias

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ST monitoring, ST shifts, Ventricular arrhythmias

Outcome measures

Primary outcome

Among patients with an appropriate ICD therapy (shock or ATP) for ventricular tachycardia or fibrillation, determine the proportion of patients who have characterized ST segment changes from baseline prior to the therapy.

Secondary outcome

- Compare the prevalence of ST segment changes between polymorphic VT/VF to monomorphic VT.

- Among the patients that received ICD shock therapy, determine the number, percentage and type of all inappropriate shocks and characterize the ST segment changes prior to these events when data is available.

- Comparison of study endpoint analysis against dobutamine stress echo results

- Number, duration and results of all ER/hospital visits due to shocks

- All-cause hospitalizations

- Adverse Events

- Deaths

Study description

Background summary

A recently introduce feature available in some ICDs manufactured by St Jude medical enables the constant beat to beat monitoring of the intra-cardiac ST segment using the implanted ICD leads. Similar systems have demonstrated this approach to be a reliable method of identifying ischemic events(19). However,

the predictive value of the ST monitoring feature in identifying pending arrhythmic events has yet to be established.

Study objective

The purpose of this investigation is to determine the prevalence of device-recorded ST segment changes occurring before appropriate ICD therapies (ATP or Shock) and to define their temporal relationship to ventricular arrhythmias.

Study design

Observational multicenter non randomized trial

Study burden and risks

There is no additional risk for the patient.
The burden consists of the additional hospital visits for the group of patients not using remote monitoring.

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

• The patient is implanted with an SJM ICD with ST Monitoring and ShockGuard* features (and remote care feature in case Merlin.net will be used)
• The patient, in the opinion of the investigator, will not require ventricular pacing for more than 20% of the time.
• The patient, in the opinion of the investigator, has or is at high risk of CAD.
• The patient is >= 18 years of age.
• The patient is able to provide written Informed Consent prior to any investigational related procedure.

Exclusion criteria

• The patient has longstanding persistent AF/AFl or permanent AF/AFl
• The patient has documented complete heart block.
• The patient is known to have uncontrolled ventricular bigeminy or trigeminy (PVCs on regular basis).
• The patient has severe Left Ventricular Hypertrophy resulting in interventricular conduction defect (IVCD).
• The patient has intermittent bundle branch blocks (BBB).
• The patient is unable to comply with the follow up schedule.
• The patient is participating in another investigational device or drug investigation.
• The patient is pregnant or is planning to become pregnant during the duration of the investigation.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-04-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	29-01-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NCT01685047
CCMO	NL42233.018.12