# PSYCHE-ICD study (Psychiatric SYmptoms in Congestive Heart failure: Evaluation in ICD recipients)

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Heart failures |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON38242

**Source**
ToetsingOnline

**Brief title**
PSYCHE-ICD study

### Condition

- Heart failures
- Mood disorders and disturbances NEC

**Synonym**
heart failure, ventricular tachyarrhythmias

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Heart failure, ICD, Psychiatric Symptoms

## Outcome measures

### Primary outcome

Primary study parameters are:

- the occurence of ventricular tachyarrhythmias

- parameters for depression

- parameters for anxiety

### Secondary outcome

Secondary study parameters are

- congestive heart failure parameters

- parameters for inflammation

- parameters for sympathetic tone

- occurrence of hospitalisation (due to heart failure)

- occurrence of atrial tachyarrhythmias

- death

# Study description

### Background summary

The number of patients suffering from heart failure is steadily increasing in

Western civilized countries, amongst others due to the introduction of the implantable cardioverter defibrillator (ICD). The ICD has had a major impact on survival and, as a consequence, on treatment of patients with ischemic and non ischemic cardiomyopathy (CMP). Prevention of SCD by means of an ICD has been implemented for this population in the ACC/AHA/ESC guidelines, resulting in an exponential growth in ICD implantations and concomitant costs. However, only 35% of implanted patients receive ICD therapy for a life threatening ventricular arrhythmia during the first three years of follow up. As the majority of patients remains free from ICD therapy, a further refinement of criteria is needed to select those patients who are most likely to benefit from this treatment modality.

Currently, effort is put into the development of enhanced risk stratification methods which assess myocardial electrical instability (e.g. microvolt T-wave alternans, signal averaged electrocardiogram and more recently short-term variability of repolarization duration), and indicators of pathophysiological substrates related to electrical instability (e.g. scar burden, ischemia, altered mechanical function, and innervation defects). Over the last decade, however, a growing interest has developed for the interplay between psychological status and heart failure, leading to the notion that the presence of psychological disorders -especially depression and anxiety- might significantly affect disease burden and prognosis in heart failure.

Several mechanisms have been proposed connecting these psychiatric disorders to somatic effects in heart failure patients. The most important are 1). Sympathetic * parasympathetic dysbalanceand 2). Inflammation. Unraveling these relationships might open new possibilities for selection of patients at increased risk for ventricular tachyarrhythmias. In addition, it may aid in development of novel treatment options for this patient group both in cardiological and psychiatric directions thus relieving disease burden and improving quality of life. The present study is designed to investigate the aforementioned interplay in heart failure patients eligible for ICD implantation.

Study hypothesis
We hypothesize that :
1). CHF patients suffering from depression or anxiety disorders are at increased risk for adverse outcome, in particular for ventricular tachyarrhythmias.
2). the interplay between depression or anxiety and poor CHF prognosis is related to both sympathetic-parasympathetic dysbalance and inflammatory status.
3). for a subset of patients the ICD implantation, either by itself or due to therapy (*shocks*) administered by the device, results in development of symptoms of depression or anxiety. The likelihood of symptom development depends on type of personality.

## Study objective

The primary objective of the study is to relate depression and anxiety in CHF patients receiving an ICD to the occurrence of ventricular tachyarrhythmias.

Secondary objectives of the study are:
Assessment of the effects of depression and anxiety on
- Worsening heart failure
- Mortality
- Occurrence of atrial tachyarrhythmias
Assessment of the relations between depression and anxiety, CHF (in particular ventricular tachyarrhythmias) and:
- the sympathetic system
- inflammatory response
Assessment of the effects of device implantation and device therapy (*shocks*) on depression and anxiety

## Study design

This is a single center prospective multecenter observational study. The period of observation is set to 3 years.

## Study burden and risks

The burden of participation in this study is estimated to be low.
- Study visits are only scheduled together with regular follow up visits. No additional visits are planned.
- A study visit will take approximately an additional 60-90 minutes (30-45 minutes for questionnaire, 30 minutes for additional somatic assessment, 30 mintues for a test that registers the hartrhythm and blood pressure by doing a few simple exercises (autonomic function testing) and ECG.
- Additional blood tests will only be taken when a regular follow up venapuncture is performed (i.e. additional blood drawn, but no additional venapunctures). At baseline and after 1 year an extra blood tube will be taken for biomarkers (sorry material). Separate informed consent is possible.
- At baseline and after 1 year a hairsample will be taken(from the head) is taken (separate informed consent possilbe).
- An ECG of 4 min. will take place annually.

The risk of participation in this study is estimated to be extremely low (no known possible adverse effects).

# 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

All patients eligible for ICD implantation.
The study is designed to evaluate patients with CHF.
Other patients eligible for ICD but without CHF will also be included to serve as an additional control group.

## Exclusion criteria

Patients unwilling to participate.
Patients in whom it is unlikely to obtain follow-up data (eg insufficient mastery of the dutch language, ICD follow up in other hospital).

# Study design

## Design

| | |
|---|---|
| Study type: | Observational invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Prevention |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 09-01-2012 |
| Enrollment: | 240 |
| Type: | Actual |

# Ethics review

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|---|---|
| Approved WMO Date: | 06-10-2011 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 26-04-2012 |
| Application type: | Amendment |
| 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 |
| --- | --- |
| CCMO | NL34386.029.11 |