PROFID EHRA

THE PROFID EHRA TRIAL

PREVENTION OF SUDDEN CARDIAC DEATH AFTER MYOCARDIAL INFARCTION BY DEFIBRILLATOR IMPLANTATION

This project has received funding from the European Union´s Horizon 2020 research and innovation programme under grant agreement No. 847999.

The PROFID EHRA trial is embedded in the large project PROFID, funded by the European Commission within the Horizon 2020 EU research and innovation programme, which is expected to change sudden cardiac death (SCD) prevention in clinical practice.

CURRENT CLINICAL GUIDELINES

A severely reduced left ventricular ejection fraction (LVEF) after myocardial infarction (MI) was shown to indicate a higher risk for SCD and led to international guideline recommendations for routine implantation of defibrillators for primary prevention of SCD.

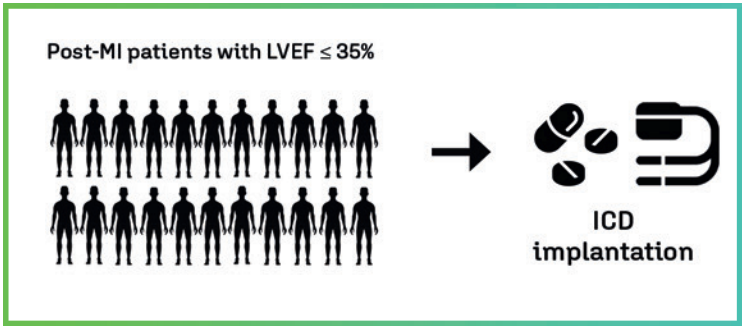

Figure 1: Current strategy for primary prevention of SCD

BACKGROUND AND RATIONALE

>> Only a minority of post-MI patients with LVEF ≤ 35% that currently receive a prophylactic implantable cardioverter defibrillator (ICD) will ever need the device – others are only exposed to potentially severe complications due to the implantation.

>> Existing data are outdated and do no longer represent current therapies, since SCD risk decreased during the last decades as a result of improved patient therapy.

>> Risk-benefit of routine defibrillator implantation for primary prevention of SCD in patients with reduced LVEF has substantially changed during the last years, due to the change in the medical treatment of post-MI patients and constant complication rates associated with defibrillator therapy.

>> A novel randomised adequately powered assessment of the role of the defibrillator under contemporary optimal medical therapy (OMT) appears imperative.

OUR STRATEGY

PROFID is expected to change SCD prevention in clinical practice.

1. Evaluate in a randomised controlled clinical trial the potential benefit or harm of routine prophylactic ICD implantation for primary prevention of SCD in the setting of contemporary OMT in post-MI patients with reduced LVEF ≤ 35%.
2. Explore the potential of novel and promising risk markers for personalised risk prediction of SCD in two optional sub-studies (a cardiac Magnetic Resonance Imaging sub-study and a sub-study on genomics) and perform an artificial intelligence-based analysis of the twelve-lead Electrocardiograms (ECGs).
3. Address ethical and legal aspects, including patients' perspective on randomised therapy strategies for SCD prevention.
4. Evaluate the economic impact to guide treatment decisions in patients with reduced LVEF ≤ 35%.
5. Update corresponding European clinical guidelines on SCD prevention and ICD implantation.

www.profid-project.eu

THE PROFID EHRA TRIAL

Non-inferiority clinical trial with randomised comparison of OMT versus ICD implantation plus OMT in post-MI patients with LVEF ≤ 35% who would receive an ICD according to current clinical guidelines.

>> Industry-independent without commercial interest or marketed products in focus

>> Publicly funded (EU Horizon 2020)

>> Investigator-driven

The PROFID EHRA trial is designed to be as close to routine clinical care as possible to represent daily routine clinical care in an optimal way.

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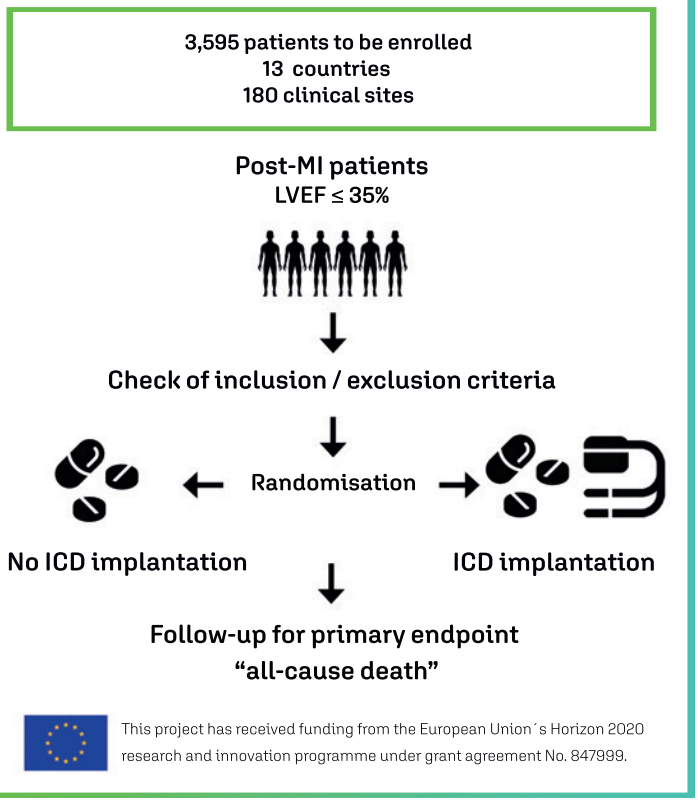

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Figure 2: Study design of the PROFID EHRA trial

OUR AIM

>> Reassess the role of routine prophylactic ICD implantation in patients with reduced LVEF ≤ 35% after myocardial infarction under contemporary OMT.

"The PROFID EHRA trial will provide urgently needed contemporary data on sudden cardiac death prevention by defibrillator implantation after myocardial infarction and is expected to profoundly influence clinical practice."

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