

EU-CERT-ICD: Comparative Effectiveness Research to Assess the Use of Primary Prophylactic Implantable Cardioverter Defibrillators in Europe

Summary:

An estimated 500,000 sudden cardiac deaths (SCD) occur each year in the European Union. Patients at risk for SCD may benefit from prophylactic treatment with an implantable cardioverter-defibrillator (ICD). ICD implantations have dramatically increased in recent years leading to multi-billion Euros of costs. Information on risks, benefits and costs supporting current guideline recommendations may be outdated which motivates the present major European study.

EU-CERT-ICD (Comparative Effectiveness Research to Assess the Use of Primary Prophylactic Implantable Cardioverter Defibrillators in Europe) aims to generate contemporary clinical outcome data on ICD effectiveness in Europe. Clinical outcomes including all-cause mortality, appropriate and inappropriate ICD shocks, and quality of life (QoL) are assessed by:

* a prospective study of patients undergoing indicated ICD treatment for primary SCD prevention, with a control group of patients not undergoing ICD treatment

* a large European registry collecting available data on prophylactic ICD treatment

* meta-analyses of available and emerging ICD outcome studies

Outcomes in patients receiving ICDs for primary SCD prevention will be compared in sub-strata, and with patients fulfilling guideline criteria but not undergoing therapy as per prior decision of treating physicians. Sub-groups with particularly large or small benefit from ICD implantation will be identified using risk markers and clinical characteristics with specific emphasis on gender.

QoL-adjusted cost-effectiveness will be estimated from actual cost comparisons and Markov decision models with attention to sub-groups, regional, and sex comparisons. The health economic part of the EU-CERT-ICD study is conducted by the Institute for Social Medicine, Epidemiology and Health Economics of the Charité Berlin.

EU-CERT-ICD is expected to provide important novel information to validate or challenge current guideline indications for primary prophylactic ICD treatment.

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Cooperation:

Biometrics:

Project duration:

2013-2018

Project status:

publication phase

Funding:

European Union

Publication:

<http://www.eu-cert-icd.eu/>

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