World-Wide Randomized Antibiotic Envelope Infection Prevention Trial

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The primary study objective is to compare the rate of major CIED infections through 12-months post-implant between the TYRX envelope group and the control group.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON42232

Source
ToetsingOnline

Brief title
WRAP-IT

Condition

- Cardiac arrhythmias
- Hepatobiliary neoplasms malignant and unspecified

Synonym
Infection after CIED implantation

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic Trading NL BV
Source(s) of monetary or material Support: Sponsor: Medtronic

Intervention

Keyword: Antibiotic, cardiovascular implantable devices, envelope

Outcome measures

Primary outcome

The primary study objective is to compare the rate of major CIED infections through 12-months post-implant between the TYRX envelope group and the control group.

Secondary outcome

Secondary objectives

- Confirm that the TYRX envelope does not increase the CIED procedure-related or system-related complication rate through 12-months post-procedure.

- Compare the major CIED infection rate during the entire follow-up between the TYRX envelope group and the control group.

- Compare the rate of major and minor CIED infections through 12-months post-procedure between the TYRX envelope group and the control group.

Ancillary objectives

- Compare all-cause mortality rates between the TYRX envelope group and the control group

- Evaluate the CIED procedure success rate in the TYRX envelope group and the control group

• Control: device and leads all implanted

• Treatment: TYRX envelope, device, and leads all implanted

- Summarize the adverse events

- Identify the predictors of CIED infection

- Summarize quality of life

- Evaluate the cost effectiveness of the TYRX envelope

Study description

Background summary

Over the last few decades, there has been a growing evidence of the importance of Cardiac Implantable Electronic Devices (CIEDs) in improving both quality of life and survival among patients with heart disease.[1] [2] This has resulted in expansion of the indications for CIED implant which is reflected in the most recent guidelines from the American College of Cardiology / American Heart Association/Heart Rhythm Society for CIED implantation and its most recent update.[3] 4 In the United States, recent data estimate that in 2011 about 350,000 patients underwent a permanent pacemaker (PPM) implant, and about 210,000 underwent an implantable cardioverter defibrillator (ICD) implant (in press). With expanding indications for these devices and an increasingly aging population, more devices are implanted for older patients with more comorbidities.5 6 This growth of newly implanted CIEDs has led to an increased recognition and awareness of associated complications, and infection is among the most important. Growing indications for CIEDs, coupled with an older and sicker patient population, contributed to significant increase in the rate of CIED infection cases. These infections are very serious as they are associated with significant morbidity and mortality and represent a significant financial burden on an already ailing health care system.

Study objective

The primary study objective is to compare the rate of major CIED infections through 12-months post-implant between the TYRX envelope group and the control group.

Study design

The World-wide Randomized Antibiotic EnveloPe Infection PrevenTion Trial (WRAP-IT) is a randomized, prospective multi-center, single blinded, post-market, interventional clinical study.

Intervention

The study intervention is the randomization and the placement of the TYRX envelop with the (planned) CIED (re)placement in the testgroup.

Study burden and risks

The burden and risc related to the study can be divided into 3 categories: surgery related, CIED implant related and TYRX envelope related.
Since all patient will undergo a CIED implant procedure only the TYRX envelope burden and risks are applicable for this section. A list of foreseen adverse events can be found in the protocol Appendix G. A risk-to-benefit analysis can be found in section 10.3 of the protocol.

Since the study is randomized, these risks are only applicable for the treatment group. No extra burden or risks are expected for the control group.

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

- Patient is at least 18 years old
- Patient is planned to undergo at least one of the following:
a. Patient has existing CIED and is undergoing IPG (including CRT-D), ICD or CRT-D replacement or upgrade with a new Medtronic generator.
i. Subjects planned to have leads added, or extracted and added for upgrades can be enrolled.
OR
b. Patient will undero a de novo Medtronic CRT-D system implant per approved indications
OR
c. Patient has an existing study eligible Medtronic CIED in which the pocket was not accessed within the last 365 days, and is undergoing pocket or lead revision.

Exclusion criteria

- Known allergy to minocyclin or rifampin or their derivates, or any other known contraindications to implantation of the TYRX envelope
- Current therapy with chronic oral immunosuppressive agents or >= 20 mg/day of Prednisone or equivalent.
- Hemodialysis or peritoneal dialysis
- Prior cardiac transplantation or existing ventricular assist device (VAD)
- Require long-term vascular acces for any reason
- Prior history of a CIED infection, other prosthetic device infection, or endovascular infection, including endocarditis, in the past 12 months.
- Physical, clinical, or laboratory signs or symptoms consistent with an active infection (including, but not limited to pneumonia, urinary tract, cellulitis, or bacteremia)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2015
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	TYRX absorbable envelope
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-07-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL52063.100.15