World-wide clinical trial about the TYRX Absorbable Antibacterial Envelope

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Medtronic , Inc. is sponsoring the World-wide Randomized Antibiotic Envelope Infection Prevention Trial (WRAP-IT), a randomized, prospective, multi-center, single blinded, post-market, interventional clinical study. This study will evaluate the...

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25621

Bron
NTR

Verkorte titel
WRAP-IT

Aandoening

Cardiovascular Implantable Electronic Device (CIED) infections

Ondersteuning

Primaire sponsor: Medtronic
Overige ondersteuning: Fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The first occurrence of a major CIED infection.
CIED infections are defined as (1) superficial cellulitis in the region of the CIED pocket with

wound dehiscence, erosion, or purulent drainage, (2) deep incisional or organ/space (generator pocket) surgical site infection that meets the Centers for Disease Control and Prevention criteria, independent from time of surgery, (3) persistent bacteremia, or (4) endocarditis.

Major CIED infections are defined as a CIED infection resulting in one or more of the following:

•CIED system removal
•Any invasive procedure (e.g. pocket opened) without system removal
•Treatment with antibiotic therapy if the subject is not a candidate for system removal and infection recurrence after completion of antibiotic therapy or evidence of deep infection with wound dehiscensce, erosion, or purulent drainage
•Death

Toelichting onderzoek

Doel van het onderzoek

Medtronic , Inc. is sponsoring the World-wide Randomized Antibiotic Envelope Infection Prevention Trial (WRAP-IT), a randomized, prospective, multi-center, single blinded, post-market, interventional clinical study. This study will evaluate the ability of the TYRX envelope to reduce major CIED infections through 12-months post-procedure following CIED generator replacement, upgrade, revision, or de novo CRT-D implant. Additionally, this large device study provides the unique opportunity to prospectively characterize the performance of Medtronic's lead monitoring features in subjects whose CIED system includes a transvenous RV defibrillation lead. Finally, the WRAP-IT study will serve as a post-approval study for those geographies requiring a post-approval study of the TYRX envelope.

Onderzoeksopzet

The first occurrence of a major CIED infection. [Time Frame: Implant to 12 months]

The first occurrence of a major or minor CIED infection [Time Frame: Implant to 12 months]

The first occurrence of a CIED procedure related or system related complication [Time Frame: Implant to 12 months]

Onderzoeksproduct en/of interventie

•Active Comparator: TYRX envelope
The Medtronic TYRX Absorbable Antibacterial Envelope is an absorbable sterile prosthesis designed to hold a pacemaker pulse generator or defibrillator to create a stable environment when implanted in the body. The purpose of the absorbable coating is to act as a carrier for the antimicrobial agents.

Intervention: Device: TYRX Absorbable Antibacterial Envelope

•No Intervention: Control

No TYRX envelope, bare CIED

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

•Patient is willing to sign and date the study PIC form

•Patient is at least 18 years of age and meets age requirements per local law

•Patient is planned to undergo at least one of the following:

a. Patient has existing CIED and is undergoing IPG (including CRT-P), 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 undergo a de novo Medtronic CRT-D system implant per approved indications

OR

c. Patient has existing study eligible Medtronic CIED in which the pocket was not accessed within the last 365 days, and is undergoing pocket or lead revision

•Willing to provide the contact information for the physician who provides followup for his/her CIED

•Willing and able to comply with scheduled follow-up and study related activities

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

•Known allergy to minocycline or rifampin or their derivatives, or any other known contraindications to implantation of the TYRX envelope.

•Current therapy with chronic oral immunosuppressive agents or ≥ 20mg/day of Prednisone or equivalent.

•Hemodialysis or peritoneal dialysis.

•Prior Cardiac transplantation or existing Ventricular Assist Device (VAD).

•Require long-term vascular access 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)

•Systemic lupus erythematous, because minocycline has been reported to aggravate this condition

•Female patient who is pregnant, or of childbearing potential and not on a reliable form of birth control. Women of childbearing potential are required to have a negative pregnancy

test within 7 days prior to device procedure

•Participation in another study that may confound the results of this study. Coenrollment in concurrent trials is only allowed when documented pre-approval is obtained from the Medtronic study manager.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	7764
Type:	Onbekend

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5096
NTR-old	NTR5228
Ander register	ClinicalTrials.gov : NCT02277990

Resultaten