# World-wide clinical trial about the TYRX Absorbable Antibacterial Envelope

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Other |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON25621

**Source**
NTR

**Brief title**
WRAP-IT

**Health condition**

Cardiovascular Implantable Electronic Device (CIED) infections

### Sponsors and support

**Primary sponsor:** Medtronic
**Source(s) of monetary or material Support:** Fund = initiator = sponsor

### Intervention

### Outcome measures

**Primary outcome**

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

**Secondary outcome**

•The first occurrence of a major or minor CIED infection
Major CIED infections are defined above. Minor CIED infections are defined as CIED infections that do not meet the definition of a major CIED infection

•The first occurrence of a CIED procedure related or system related complication

◦A CIED system related event is defined as an adverse event related to the CIED system which includes the device, leads, implant tool(s), programmer, or TYRX envelope (if applicable)

◦A CIED procedure related event is defined as an adverse event that occurs due to any procedure related to the implantation or surgical modification of the system including the TYRX envelope (if applicable)

◦A procedure or system related complication is defined as an adverse event related to a CIED procedure or the CIED system that results in at least one of the following:

Death,Termination of significant device function, Invasive intervention

# Study description

**Study objective**

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.

**Study design**

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 ]

**Intervention**

•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

# Contacts

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# Eligibility criteria

## Inclusion criteria

•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

## Exclusion criteria

•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.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Other |
| Start date (anticipated): | 01-01-2015 |

| | |
|---|---|
| Enrollment: | 7764 |
| Type: | Unknown |

## Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

## 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 |
|---|---|
| NTR-new | NL5096 |
| NTR-old | NTR5228 |
| Other | ClinicalTrials.gov : NCT02277990 |

## Study results