INGEVITY

NCT01688843

Principal Investigator: Dr. Asim Yunus, MD (Covenant)

Condition: Bradycardia, Sinus Node Dysfunction

Device: INGEVITY lead

Official Title: Safety and Performance Study of the INGEVITY Lead

Sponsor: Boston Scientific Corporation

Purpose: The objective of this study is to gather data to establish the safety, performance and effectiveness of the INGEVITY pace/ sense leads.

Inclusion Criteria:

- Subject is willing and capable of providing informed consent
- Subject has a Class I or II indication for implantation of a single(VVI (R) only) or dual chamber pacemaker or a CRT-P system according to the ACC/AHA/HRS, or ESC guidelines
- Subject is willing and capable of participating in all testing/ visits associated with this clinical study at an approved clinical study center and at the intervals defined by this protocol
- Subject is age 18 or above, or of legal age to give informed consent specific to state and national law

Exclusion Criteria:

- Subject has or has had any pacing or ICD system implants
- Subject has a sensitivity to dexamethasone acetate (DXA)
- Subject has a mechanical tricuspid heart valve
- Subject is enrolled in any other concurrent study, with the exception of local mandatory governmental registries and observational studies/registries
- Subjects with documented permanent or persistent AF where the physician intends to implant dual chamber pulse generator (single chamber VVIR pulse generators in these subjects is acceptable)
- Subject is currently on the active heart transplant list
- Subject has documented life expectancy of less than 12 months
- Women of childbearing potential who are or might be pregnant at the time of study enrollment or INGEVITY Lead implant
- Subjects currently requiring dialysis

Source: https://clinicaltrials.gov/ct2/show/NCT01688843
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