CRT-DRIVE: Cardiac Resynchronization Therapy DeliveRy guided by non-Invasive electrical and VEnous anatomy assessment

Published: 12-06-2024
Last updated: 30-01-2025

The primary objective of the CRT-DRIVE study is to test the hypothesis that at least 75% of patients undergoing a CRT implantation guided by non-invasive electrical and venous anatomy assessment (XSPLINE technology) will show a reduction of left...

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON56818

Source
ToetsingOnline

Brief title
CRT-DRIVE

Condition

- Heart failures

Synonym
Symptomatic heart failure

Research involving
Human

Sponsors and support

Primary sponsor: XSpline S.p.A.

Source(s) of monetary or material Support: Industry: XSpline S.p.A.

Intervention

Keyword: Cardiac Resynchronization Therapy, Patient-tailored CRT implantation, Symptomatic heart failure

Outcome measures

Primary outcome

The primary endpoint is to achieve a reduction of left ventricular end-systolic

volume of at least 15% at 6-month follow-up in 75% of CRT treated patients.

Secondary outcome

Secondary endpoints are the following:

1. determine the feasibility of the systematic use of a cloud-based analysis

tool of non-invasively acquired electrical (standard 12-lead ECG) 3-dimensional

biventricular activation and cardiac anatomy including coronary sinus, coronary

veins, and bi-ventricular geometry.

2. evaluate the CRT procedural time.

3. determine the total X-ray exposure time.

Study description

Background summary

Cardiac resynchronization therapy (CRT) is considered an established non-pharmacological treatment for heartfailure (HF). However, clinical research efforts continue with the goal to further improve CRT clinical efficacy.
The standard 12-lead electrocardiogram (ECG) is the most routinely used, inexpensive, and non- invasive modality to record the electrical activity of the heart, but its diagnostic capability has acknowledged limits.
Non-invasive electrocardiographic imaging, also called ECGI mapping, overcomes at least some of the limitations of the standard ECG. However, ECGI mapping relies on a large number of electrodes, placed on the patient*s torso at the

time of geometry acquisition using cardiac imaging as well as during the clinical intervention, thus requiring dedicated technical support and additional costs. Therefore, despite the advantages, its adoption in the clinical workflow is still limited.
More recently, a novel approach has been developing which enables to reconstruct the activation map relying only on the 12-lead ECG for the electric data, by taking advantage of physiological and anatomical knowledge implemented in a patient-specific model. The fitted patient-specific model can calculate almost real-time the activation sequence and may therefore enable model-assisted therapeutic intervention.
XSpline® Cloud is a cloud-based Software as a Medical Device for medical professionals, specifically cardiologist.
The software XSpline® Cloudis provided in form of a platform, a stand-alone medical software package used to collect, archive and display clinical information and health documentation referring to CRT-destined patients. XSpline® Cloud, given DICOM CT images of torso and heart, and given digital 12-lead electrocardiogram, provides visual 3D information about heart anatomy and the morphology of coronary vein through an automatic segmentation procedure of cardiac structures. Additionally, it generates an epi- and endocardial electrical activation map, which provides an opportunity to visualize the latest activation zone and reach the target zone for successful CRT implantation. It is therefore an active medical device- non therapeutic - used for image and data elaboration purposes in the office of the physician. The clinical benefits expected for CRT-destined patients is to receive the intervention with higher prior knowledge of the surgeon regarding heart and veins anatomy and electrical functionality, with the potential of a more accurate intervention and reduced time.

Study objective

The primary objective of the CRT-DRIVE study is to test the hypothesis that at least 75% of patients undergoing a CRT implantation guided by non-invasive electrical and venous anatomy assessment (XSPLINE technology) will show a reduction of left ventricular end-systolic volume of 15% or more at 6-month evaluation.

Study design

This is a prospective, multicenter controlled study. Enrolled patients are eligible for CRT as part of their standard of care and, additionally, meet all the other inclusion criteria and do not meet any of the exclusion criteria. After the 6-months follow-up visit, all included and treated patients will complete and exit the study. No further follow-up visit is envisioned thereafter

Study burden and risks

For patients, the risk implicit in the participation in the clinical investigation is the possible malfunction of the web connection and/or the software. As a result, the Investigator can be provided with invalid data. This potential issue is minimized by using data exchange protocols with various data protection protocols, vasty checked though intensive testing that protects transfer and integrity of data. Image quality of output data (resolution, orientation, artefacts) is checked, extensively tested, improved using robust image improvement algorithms and validated.
In addition, patient personal information is not required for the use of the device. Whenever patient information is present on uploaded images, that is overwritten by a codification during the upload, therefore no patient information is stored.
By participating in this clinical investigation, patients will benefit from the use of a tool that will provide the Investigator with more precise mapping of electrical activity of the heart and of coronary venous anatomy. This will help in a more appropriate positioning of the LV lead and cannulation of the coronary sinus. This will contribute to reduction of total procedure length and fluoroscopy time

Risks from Electrocardiogram (ECG)
The ECG test is a recording of the electrical activity of the heart. The sticky pads used may be cold when applied and sometimes cause discomfort such as redness or itching. If the hair under the patches needs to be shaved, irritation from shaving also could occur.
Risks from Computerized Tomography (CT)
A CT scan is a series of cross-sectional X-rays that will be taken of the heart. CT scans expose the patient to more radiation than a standard X-ray, but the risk of complication including cancer associated with this irradiation is small. Some people have a reaction to the contrast dye that is injected into a vein before the scan, as it contains iodine. Allergy to iodine may cause nausea, sore throat, vomiting, sneezing, itching or hives. A severe allergic reaction (called anaphylaxis) that results in difficulty breathing can occur, but it is rare.
Disadvantages of this study such as physical complications are no different from patients not participating in this study.

Contacts

Public
XSpline S.p.A.

Via Josef Ressel 2/F
Bolzano (BZ) 39100
IT

Scientific
XSpline S.p.A.

Via Josef Ressel 2/F
Bolzano (BZ) 39100
IT

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Informed Consent signed by the subject
• Age >=18 years at time of consent.
• CRT indication according to the 2021 ESC guidelines on cardiac pacing and CRT (class I and
IIA indication in patients with LBBB QRS morphology) or to 2017 AHA/ACC/HFSA guidelines
(COR I).
• Patients in Sinus Rhythm, who are scheduled for CRT device implantation in less than 3
months.
• QRS duration >=130 ms
• Left bundle branch block
• Left ventricular ejection fraction <=35%
• Symptomatic heart failure NYHA class >= II
• Documented stable medical treatment for at least 6 months
• No cardiovascular intervention during the last 6 months

Exclusion criteria

• History of persistent or permanent atrial fibrillation • Previous pacemaker

or ICD implantation • Indication to pacing due to bradycardia • Patients considered for His bundle pacing or cardiac conduction pacing • Patients with unstable angina • Subject experienced a recent myocardial infarction, within 40 days prior to enrollment • Subject underwent coronary artery bypass graft or valve surgery, within 90 days prior to enrollment • Subject is post heart transplantation, or is actively listed on the transplantation list, or has reasonable probability (per investigator*s discretion) of undergoing transplantation in the next year • Subject is implanted with a left ventricular assist device • Subject is on continuous or uninterrupted infusion (inotropic) therapy for heart failure • Subject has severe aortic stenosis (with a valve area of <1.0 cm2 or significant valve disease expected to be operated within study period) • Subject has congenital heart disease • Subject has a mechanical right-sided heart valve • Subject has a life expectancy of less than one year in the opinion of the investigator • Pregnant or breastfeeding women, or women of child bearing potential and who are not on a reliable form of birth control • Subject is enrolled in one or more concurrent studies that would confound the results of this study • Patients who have contraindications to CT scanning. • Patients with chronic kidney diseases and estimated glomerular filtration rate (eGMR) calculated based on CKD-EPI 2009 < 40 ml/min/1.73m2 • Patients with diseases of the thyroid gland with impaired T3 and T4 levels

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2023
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	XSpline® Cloud

Registration:	No

Ethics review

Approved WMO Date:	12-06-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT05327062
CCMO	NL84198.000.23