DANISH-CRT – Substantial protocol amendments, 06052026

Does targeted positioning of the LV pacing lead towards the latest local electrical activation when implanting CRT devices reduce the incidence of the combined endpoint "death or non-planned hospitalisation for heart failure" in patients with heart failure and prolonged QRS?
A Danish national randomised study

ClinicalTrials.gov NCT 03280862

Substantial protocol amendments

11-10-2017	ClinicalTrials.gov NCT added. Contrast-enhanced CT scan will be performed after implantation rather than flash CT scan without contrast as previously stated. Amount of contrast according to GFR level is specified to minimize risk of impaired kidney function. In patients with significantly impaired kidney function (estimated GFR <30ml/min/1,73 m2), no CT scans will be performed.
11-01-2018	PRO questionnaires are omitted at 12MFU and further questionnaires added at 6/24/48MFU. Study budget is increased with DKK 1.000.000 for GCP monitoring. In the section on Study design, it is specified that pre-operative echocardiography is also to verify LVEF ≤35%, and in both treatment groups, the implanting physician will have access to a clinical standard echocardiography description for evaluation of scar tissue. In the Follow-up section, a time frame of +/- 30 days for follow-up visits is added.
24-10-2019	Post implantation CT scan must be performed no later than at 3 months follow-up. Initially, post implantation CT scan was planned prior to discharge after implantation or <2 weeks in patients with impaired kidney function (GFR 30-45 ml/min/1,73 m2).
27-09-2021	Unless contraindicated, the patients will initiate treatment with SGLT2 inhibitors. This is added to the protocol as an Addendum to the guideline on medical treatment for heart failure (protocol p. 29, please find an English version below). Based on grants from the Danish Heart Foundation (2 x 1.500.000 DKK) and the Novo Nordisk Foundation (8.367.450 DKK), the section on Economics is adjusted.
19-01-2023	Prolongation of the study period through 31-12-2026. The section on Economics is adjusted based on financial support (DKK 1.000.000) from the Danish Pacemaker and ICD Registry (DPIR).
16-10-2024	The section on Economics is adjusted based on a grant (DKK 500.000) from Arvid Nilssons Foundation

During the course of the study, there have been changes to the composition of the steering committee:

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Addendum to Guidelines for Medical Treatment of Heart Failure (p. 29)

Following several large-scale randomized trials documenting a survival benefit of SGLT2 inhibitor treatment in patients with heart failure, recommendations for their use have been included in the latest European guidelines (2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure).
On this basis, patients in the DANISH-CRT study will initiate SGLT2 inhibitor treatment, unless contraindicated.
For patients referred for CRT implantation and included in DANISH-CRT, SGLT2 inhibitor treatment is initiated immediately, either before or shortly after implantation.
For patients already included in the study and undergoing post-implantation follow-up, SGLT2 inhibitor treatment is initiated in all patients whose most recent echocardiography showed LVEF <40%.
In these patients, this therapy is a Class I (A) indication.
The registration of SGLT2 inhibitor treatment will be incorporated into the study's Case Record Form (CRF).