Mechanistic insight in left ventricular septal and left bundle branch pacing.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23434

Source
NTR

Brief title
MASTER-LV

Health condition

Bradycardia, Heart Failure, Left bundle branch block

Sponsors and support

Primary sponsor: Medtronic
Source(s) of monetary or material Support: Company (Medtronic)

Intervention

Outcome measures

Primary outcome

To demonstrate superiority of left ventricular septal pacing (LVSP) over RV pacing and to investigate the additional effect of capturing the left bundle branch in LVSP. This will be done by studying differences in electrophysiological and hemodynamic effects of different LV septal pacing lead penetration depths.

Secondary outcome

• Study the global and regional strain patterns measured by echocardiography during LVSP.
• Compare effects of LVSP between patients with structurally normal hearts and patients with reduced LV ejection fraction.
• To study ventricular remodelling assessed through echocardiography after three months in all patients.

Study description

Background summary

Recent studies have described left ventricular septal pacing deep in the interventricular septum (IVS) as a new conduction system pacing strategy. However, information on the electrophysiological and hemodynamic effects of the pacing depth within the IVS and the additional effect of capturing the left bundle branch (LBB) is unknown.
The primary objective is to demonstrate superiority of left ventricular (LV) septal pacing (LVSP) over right ventricular (RV) pacing and to investigate the additional effect of capturing the left bundle branch in LVSP. This will be done by studying differences in electrophysiological and hemodynamic effects at different LV lead penetration depths.
Secondary objective is to study differences in electrical and hemodynamic effects between patients with structurally normal hearts and patients with reduced left LV function.

Study objective

1) Left bundle branch area pacing is superior over right ventricular (RV) pacing. 2) Acute electrical and hem-dynamic effect is comparable between LV septal pacing and left bundle branch pacing.

Study design

1day FU, 6 months FU

Intervention

Left bundle branch area pacing

Contacts

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Eligibility criteria

Inclusion criteria

Indication for permanent cardiac pacing:
o pacing indication in structurally normal heart because of:
• sinus node dysfunction (SND)
• atrioventricular block (AVB)
• atrial tachy-arrhythmia refractory to anti-arrhythmic medications that required atrioventricular node ablation
o Pacing indication with reduced LV ejection fraction
• pacing indication with reduced LV ejection fraction and expected high percentage of ventricular pacing
• heart failure with wide QRS and LBBB and reduced LVEF

Exclusion criteria

• Age < 18 years
• Incapable of giving informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-05-2021
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	21-09-2021
Application type:	First submission

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	NL9748
Other	METC azM/UM : METC 20-066

Study results