Trial information
Clinicaltrials.gov (NCT04542785)
September 2020
Region Zealand Ethics committee ID: SJ-797 Internal ID number Region Zealand: REG- 078-2019
Holbaek University Hospital Odense University Hospital Hvidovre University Hospital Region Zealand University Hospital - Roskilde Region of Southern Denmark and Region Zealand joint research fund 2018 The Danish Heart foundation grant number 19-R134-A8959-22123 The University of Southern Denmark A.P. Moeller Foundation
Holbaek Hospital Smedelundsgade 60, 4300 Holbaek Hospital Denmark
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Lenient rate control versus strict rate control for atrial fibrillation. The Danish Atrial Fibrillation (DanAF) randomised clinical trial Lenient rate control versus strict rate control for atrial fibrillation. The Danish Atrial
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Denmark
Atrial Fibrillation
Lenient rate control versus strict rate control
Inclusion criteria: 1. Atrial fibrillation (ECG-confirmed and diagnosed by the treating physician) persistent (defined as atrial fibrillation for more than 7 days) and permanent atrial fibrillation (only rate control is considered going forward); 2. Rate control must be accepted as being the primary management strategy going forward. 3.Informed consent; 4.Adult (18 years or older). Exclusion criteria: 1. No informed consent; 2.Initial heart rate under 80 bpm at rest (assessed via an electrocardiogram (ECG) before randomisation); 3. Less than 3 weeks of anticoagulation with NOAC or 4 weeks with efficient warfarin; 4. Participants dependent on a high ventricular rate to maintain a sufficient cardiac output. This will be based on an

	participant. 5. Participants who are hemodynamic unstable and therefore require immediate conversion.
15. Study Type	1. Interventional study 2. Method of allocation: Randomised Masking: Participant and outcome assessors blinded Assignment: parallel Primary purpose: Comparing two strategies
16. Date of First Enrollment	Anticipated end of January 2021.
17. Sample Size	350 planned, o enrolled.
18. Recruitment Status	Pending
19. Primary Outcome(s)	Short Form-36 (SF-36) questionnaire (physical component score).
20. Key Secondary Outcomes	Secondary outcomes will be days alive outside hospital, symptom control using the Atrial Fibrillation Effect on Quality of Life, quality of life using the SF-36 questionnaire (mental component score), and serious adverse events.
21. Ethics Review	Approved on 30.10.2019 by The Ethics committee in Region Zealand. Alléen 15, 4180 Soroe. Telephone number: 57 87 52 83
22. Completion Date	Anticipated completion date January 2026
23. Summary Results	Not yet available
24. IPD Sharing Statement	Plan to Share IPD: Yes