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Atrial fibrillation ablation versus heart rate control using conduction system pacing with ablation of the atrioventricular node

Submission date 25/07/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 05/08/2024	**Overall study status** Ongoing	
Last Edited 09/06/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) impacts heart function by causing a loss of contraction and deteriorating pump function due to the irregular and often rapid heart rate. The coexistence of AF with heart failure (HF) increases the risk of hospitalization and death. Treatment strategies involve drugs to slow down heart rate or to maintain normal rhythm, catheter intervention to maintain normal rhythm (AF ablation by pulmonary vein isolation), or implantation of a pacemaker with catheter ablation of the atrioventricular node (AVNA) to allow the pacemaker to regulate the heart rate. Conduction system pacing (CSP) involves implanting the pacemaker lead directly into the heart's natural electrical conduction system, maintaining a close to normal contraction of the heart (which allows preservation of pump function).
This study evaluates a strategy of AF ablation against CSP combined with AVNA in patients with AF and HF, as these treatments have never been directly compared. The aim is to determine whether CSP with AVNA has similar rates of heart failure hospitalization and death compared to AF ablation.

Who can participate?
Patients aged 60 years and over who have persistent AF (which is continuously present for over 7 days) and HF (with at least one hospitalization or emergency room / HF clinic visit for HF in the past 2 years and elevated blood markers for HF during this interval)

What does the study involve?
Patients are randomly allocated to either AF ablation or to pacemaker implantation with CSP and AVNA. Both these treatments are performed in routine clinical practice. The patients are then followed up for at least 1 year for clinical events (hospitalizations, deaths), as well as other criteria such as quality of life.

What are the possible benefits and risks of participating?
Participants will be closely followed up. The risks involved are those of the routine procedures of the study.

Where is the study run from?
University Hospital of Geneva (Switzerland)

When is the study starting and how long is it expected to run for?
August 2022 to October 2028

Who is funding the study?
Swiss National Science Fund (Switzerland)

Who is the main contact?
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Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT06207383

Protocol serial number
SNF_2024-D0031

Study information

Scientific Title
Catheter ABlation of Atrial fibrillation versus atrioventricular nodal ablation with CondUction System pacing in persistent atrial fibrillation and heart failure (ABACUS)

Acronym
ABACUS

Study objectives
The investigation seeks primarily to determine whether Conduction System Pacing + Atrioventricular Nodal Ablation (CSP+AVNA) is superior to atrial fibrillation (AF) ablation to reduce the incidence of cardiovascular hospitalization (CVH) or mortality, and whether it is non-inferior to reduce heart failure hospitalization (HFH) or mortality, in patients with persistent atrial fibrillation (AF) and heart failure (HF).

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 16/10/2024, Commission cantonale d'éthique de la recherche (CCER) / Cantonal research ethics commission (Rue Adrien-Lachenal 8, Geneva, 1227, Switzerland; +41 (0)22 546 51 01; ccer@etat.ge.ch), ref: 2024-D0031

2. approved 26/06/2024, HUS Regional Medical Research Ethics Committee (HUS Central Archives, PO Box 200, Marjaniementie 74, Iiris Centre, , Helsinki, 00029 HUS, Finland; -; keskuskirjaamo@hus.fi), ref: HUS/4385/2024

Study design
Investigator-initiated prospective randomized controlled open-label multicentre study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Persistent atrial fibrillation and heart failure

Interventions
AF ablation is a routine procedure and may be performed according to the operator’s preference (e.g. radiofrequency ablation, cryoablation, pulsed-field ablation etc) but should include pulmonary vein isolation (PVI) and restoration of sinus rhythm as a goal. Patients may be included in the trial if they have had a single previous PVI, but any further redo procedures during the course of the trial are considered CVH endpoints. Rate and/or rhythm control medical therapy may be continued after the ablation procedure, as deemed necessary.

Randomization will be 1:1 using RedCAP with the alternative intervention of CSP + AVNA.

CSP implantation with His bundle pacing (HBP) or left bundle branch area pacing (LBBAP) is currently available in routine clinical practice and may be performed according to the operator’s preference but should include conduction system capture or left ventricular septal pacing (LVSP) as a goal. All hardware to be used are commercially available and some will soon receive regulatory approval for CSP.

AVNA is a standard procedure which may be performed during the implantation or as a staged procedure, according to operator preference.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The following primary endpoints are assessed at the last follow-up/study closure:
1. The composite of all-cause death and CVH (superiority hypothesis)
2. The composite of all-cause death and HFH (non-inferiority hypothesis)

Key secondary outcome(s))
The following secondary endpoints are measured using patient medical records at the last follow-up/study closure unless specified otherwise:
1. Individual components of the primary endpoints
2. Cardiovascular mortality
3. Duration of hospitalization for cardiovascular causes
4. Reintervention rate (atrial fibrillation [AF] ablation or device-related)
6. Need for pacemaker implantation (e.g. sinus node dysfunction following AF ablation)
7. Atrioventricular nodal ablation (AVNA) or AF ablation crossovers
8. Sinus rhythm at each follow-up
9. New York Heart Association (NYHA) class at baseline, 1 year and at end of follow-up
10. Quality of life (QOL) questionnaire measured using the Minnesota Living with Heart Failure and EQ-5D-5L at baseline and 1-year
11. Symptom classification for AF measured using the modified European Heart Rhythm Association (EHRA) score
12. Patient-reported outcome measures (PROMs) at 1 year
13. Win ratio composite endpoint analysis
14. Left ventricular ejection fraction (LVEF) at 1 year
15. Left atrial size at 1 year (long axis diameter and 4-chamber surface area)
16. Periprocedural complications (within 1 month of intervention)
17. Long-term complications
18. Healthcare costs and cost-effectiveness

Completion date
01/10/2028

Eligibility

Key inclusion criteria
1. Persistent AF with symptomatic HF despite medical therapy, considered to be suitable for AF ablation, with at most one previous PVI procedure
2. At least one prior hospital admission, or emergency room / HF clinic visit for HF in the past 2 years, with NT-pro-BNP >1000 pg/ml or BNP >250 pg/ml measured at any timepoint during this interval
3. Previous or current rate or rhythm control drug therapy
4. Considered eligible for CSP implantation as an alternative to AF ablation
5. Age > or = 60 years

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
60 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. NYHA Class IV and systolic blood pressure ≤80 mmHg despite optimized therapy
2. Life expectancy <2 years
3. Need for major surgical intervention
4. Myocardial infarction, stroke or percutaneous coronary intervention within the previous 3 months
5. Previously implanted or planned implantation of CRT device or pacemaker. Implantable cardioverter defibrillator (ICD) implantation without a pacing indication is acceptable.
6. Participation in another controlled trial
7. Inability to sign an informed consent form

Date of first enrolment
24/10/2024

Date of final enrolment
20/08/2027

Locations

Countries of recruitment
United Kingdom

England

Austria

Belgium

Bulgaria

Czech Republic

Finland

France

Germany

Hungary

Italy

Netherlands

Poland

Spain

Switzerland

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Sponsor information

Organisation
University Hospital of Geneva

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Charity

Funder Name
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Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (Yareta) without personal data identifiers.

IPD sharing plan summary
Stored in publicly available repository