

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/08/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/06/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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?
Prof. Haran Burri, haran.burri@hug.ch

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Haran Burri

ORCID ID
<https://orcid.org/0000-0002-4393-5338>

Contact details
Cardiology Departement
University Hospital of Geneva
Rue Gabrielle Perret Gentil 4
Geneva
Switzerland
1211
+41 (0)22 372 72 00
haran.burri@hug.ch

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT06207383

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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)

Secondary outcome measures

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

Overall study start date

16/08/2022

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

Age group

Senior

Lower age limit

60 Years

Upper age limit

100 Years

Sex

Both

Target number of participants

220

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

Austria

Belgium

Bulgaria

Czech Republic

England

Finland

France

Germany

Hungary

Italy

Netherlands

Poland

Spain

Switzerland

United Kingdom

Study participating centre

University Hospital of Geneva

Rue Gabrielle Perret-Gentil 4,

Geneva

Switzerland

1211

Study participating centre

Inselspital Bern

Freiburgstrasse 20,

Bern

Switzerland

3010

Study participating centre
Univestiy Hospital of Zurich
Rämistrasse 100
Zurich
Switzerland
8091

Study participating centre
University Hospital of Basel
Petersgraben 4
Basel
Switzerland
4031

Study participating centre
IRCCS Policlinico
S. Orsola via Giuseppe Massarenti 9
Bologna
Italy
40138

Study participating centre
Ospedale Santa Maria della Misericordia
Viale Tre Martiri 140
Rovigo
Italy
45100

Study participating centre
Ospedale Maggiore Della Carità Di Novara
Corso Mazzini 18
Novara
Italy
28100

Study participating centre
University Hospital of Ferrara
VIA A. MORO
Cona
Italy
8-44124

Study participating centre

Herzzentrum Leipzig

Strümpellstraße 39

Leipzig

Germany

04289

Study participating centre

Medizinische Fakultät OWL

Georgstr. 11

Bad Oeynhausen

Germany

32545

Study participating centre

Herzzentrum Bremen

Senator-Wessling-Str. 1

Bremen

Germany

28277

Study participating centre

Hospital Universitari i Politècnic la Fe

Avinguda de Fernando Abril Martorell, 106

Valencia

Spain

46026

Study participating centre

Hospital Clínic de Barcelona

Villarroel 170

Barcelona

Spain

08036

Study participating centre

Hospital Clínico Universitario Lozano Blesa

Avenida San Juan Bosco 15

Zaragoza
Spain
50009

Study participating centre
Hospital Universitario La Paz
P.º de la Castellana, 261
Madrid
Spain
28046

Study participating centre
University Hospital Královské Vinohrady
Šrobárova 1150 /50
Prag
Czech Republic
100 00

Study participating centre
Semmelweis University
Üllői út 26
Budapest
Hungary
1085

Study participating centre
Antwerp University Hospital
Drie Eikenstraat 655
Edegem
Belgium
2650

Study participating centre
Universitair Ziekenhuis Gent
Heymanslaan 10
Gent
Belgium
9000

Study participating centre

AZ Sint Jan

Ruddershove 10

Bruges

Belgium

8000

Study participating centre

Jagiellonian University

Jakubowskiego 2

Krakow

Poland

30-688

Study participating centre

St. Joseph's Heart Rhythm Center

Anny Jagiellonki 17

Rzeszów

Poland

35-623

Study participating centre

Heart and Lung Center, Meilahti Hospital

Haartmaninkatu 4

Helsinki

Finland

FI-00029

Study participating centre

Ordensklinikum Elisabethinen

Fadingerstraße 1

Linz

Austria

4020

Study participating centre

LKH-Univ. Klinikum Graz

Auenbruggerplatz 15

Graz

Austria

8036

Study participating centre

Acibadem City Clinic Tokuda University Hospital

bul. "Nikola Y. Vaptsarov" 51B

Sofia

Bulgaria

1407

Study participating centre

Maastricht UMC+

P. Debyelaan 25

Maastricht

Netherlands

6229

Study participating centre

National Heart and Lung Institute, Imperial College London

Guy Scadding Building, Dovehouse St

London

United Kingdom

SW3 6LY

Study participating centre

Service de Cardiologie , hôpital Charles Nicolle

1 rue de Germont

Rouen

France

76031

Sponsor information

Organisation

University Hospital of Geneva

Sponsor details

Mrs Delphine Nerfin, University Hospital of Geneva, Legal Affairs Department, Bvd de la Cluse 77

- 1211 Genève 14

Geneva

Switzerland

1211

+41 (0)79 553 17 59
haran.burri@hug.ch

Sponsor type

Hospital/treatment centre

Website

<http://www.hug-ge.ch/>

ROR

<https://ror.org/01m1pv723>

Funder(s)

Funder type

Charity

Funder Name

Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

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, SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

Results and Publications

Publication and dissemination plan

Presentation of the results in a cardiology congress (EHRA) and publication in a peer-reviewed journal

Intention to publish date

30/01/2029

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