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Neuromodulation to improve patient recovery after coronary artery bypass grafting

Submission date 13/11/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol
Registration date 13/11/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 13/11/2025	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Neuromodulation with auricular vagal nerve therapy (AVNT) is a method known to help promote relaxation and offers many benefits related to reduced anxiety and pain. This method has been tested in various patient populations, including patients with heart conditions. Studies indicated that AVNT reduces inflammation, helps improve heart rhythm disorders, and it is largely safe. In this study, we will evaluate if neuromodulation therapy delivered with the Nurosym device decreases the postoperative atrial fibrillation rates and burden and aids patient recovery after cardiac surgery.

Who can participate?
Adult patients undergoing elective on-pump isolated CABG surgery.

What does the study involve?
The participants in the intervention group will receive AVNT adjunct to standard of care preoperatively (1h), intraoperatively (1h), and postoperatively (7h daily) until the postoperative day 4. The participants in the control group will receive sham treatment (null current through the device), adjunct to standard of care.

What are the possible benefits and risks of participating?
The intervention poses none or minimal risks for participants. Participants in the intervention group will potentially benefit from improved recovery.

Where is the study run from?
Geneva University Hospitals (HUG) (Switzerland)

When is the study starting and how long is it expected to run for?
01 February 2025 – 01 May 2028

Who is funding the study?
Geneva University Hospitals (HUG) (Switzerland)

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Swissethics BASEC ID
2025-D0083

Study information

Scientific Title
Auricular vagal neuromodulation therapy (AVNT) with Nurosym for preventing postoperative atrial
fibrillation, decreasing inflammatory responses, and improving patient recovery following CABG – a
randomized controlled trial

Acronym
AVNT_CABG

Study objectives
Primary objective: Ascertain if auricular vagal neuromodulation therapy (AVNT), adjunct to standard of care, reduces the rate of postoperative atrial fibrillation (POAF) following coronary artery bypass graft (CABG) surgery
Secondary objectives: to determine if AVNT adjunct to standard of care
-is decreasing the POAF burden,
-improves inflammatory profile,
-shortens the length of ICU and hospital stay,
-increases patient comfort, by decreasing the levels of pain, preventing nausea/vomiting, and decreasing the psychological stress.

Ethics approval required

Ethics approval required

Ethics approval(s)
submitted 10/09/2025, Swissethics CCER (Commission cantonale d'éthique de la recherche) Geneva (Rue Adrien-Lachenal 8, Geneva, 1207, Switzerland; 0041 22 546 51 01; ccer@etat.ge.ch), ref: 2025-D0083

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Prevention, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Postoperative atrial fibrillation, following cardiac surgery, pain, stress

Interventions
Assignment to each of the two parallel arms will be performed based on a stratified block randomization scheme, with a stratum assigned to each sex (male/female), and a small block size (block size = 4). The randomization scheme will be generated in R (eg. “blockrand” package) and uploaded in REDCap. The assignment to experimental/control arms will be performed automatically for each new participant entry in REDcap. The randomization scheme will be concealed to the REDCap data entry user.

The intervention consists in AVNT with Nurosym device adjunct to standard of care : 1 h preoperatively, 1h intraoperatively, and 7h daily starting from their arrival in ICU or intermediate care (the day of surgery, day 0) and until postoperative day 4, with even exposure between the left and right ear.

The comparator will be sham (null current delivered by the electrode attached to tragus) adjunct to standard of care.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
Nurosym (Parasym)

Primary outcome(s)
1. POAF incidence measured using % at postoperative day 5 (cumulative for the first 5 postoperative days)

Key secondary outcome(s))
1. time from surgery to POAF onset measured using h at postoperative day 5

2. POAF burden (time spent on POAF/monitoring time) measured using % at postoperative day 5 (cumulative for the first 5 postoperative days)

3. number of POAF episodes measured using counts at postoperative day 5 (cumulative for the first 5 postoperative days)

4. longest duration of POAF episodes measured using min at (until) postoperative day 5

5. amount of opioid use measured using g at postoperative day 5 (cumulative for the first 5 postoperative days)

6. nausea /vomiting measured using % at postoperative day 5 (cumulative for the first 5 postoperative days)

7. intensive care unit or intermediate care stay measured using days at (until) postoperative day 5

8. length of hospital stay measured using days at (until) discharge

9. pain on a 0-to-10 Visual Analog Scale (VAS) measured using counts at postoperative days 2 and 5

10. psychological stress on a scale 0-to-10 measured using counts at postoperative days 2 and 5

11. Circulating markers: serum levels of C-reactive protein (CRP) measured using mg/l at 1h after surgery, and daily until day 5 postoperatively

12. high sensitivity cardiac troponin I (hs-cTnI) measured using (ng/l) at 1h after surgery, and daily until day 5 postoperatively

13. N-terminal pro-B-type natriuretic peptide (NT-proBNP) measured using ng/l at 1h after surgery, and daily until day 5 postoperatively

14. neutrophil-to-lymphocyte ratio (NLR) measured using adimensional (number) at 1h after surgery, and daily until day 5 postoperatively

15. Platelet reactivity score measured using weighted sum of adenosine diphosphate (ADP), arachidonic acid (ASPI), thrombin receptor activating peptide (TRAP) test results at day 1 and day 3 postoperatively

16. Salivary alpha amylase measured using U/ml at day 1 and day 5 postoperatively

Completion date
01/07/2028

Eligibility

Key inclusion criteria
1. Age 18 years old or older
2. Undergoing elective on-pump isolated CABG

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. History of atrial fibrillation or atrial flutter before CABG
2. Preoperative sinus node dysfunction, atrioventricular block, severe bradycardia, heart valve disease
3. Undergoing CABG combined with another type of surgery
4. Permanent pacemaker before surgery
5. Off-pump CABG
6. Undergoing urgent or emergency surgery
7. Contraindications and limitations of the Nurosym device:
- Cervical vagotomy
- Permanent metallic/electronic device (e.g., cochlear implants) or jewellery in close proximity to ear tragus
- Pregnant women
- Cerebral shunts
- Invasive vagus nerve stimulators
- Non-active metal implants potentially interacting with the nervous system (e.g., metallic spinal implants)
- Lesions (e.g., cracked skin or wounds) on the tragus
8. Vulnerable subjects (e.g., prisoners)
9. Inability of the subject to consent or to follow the procedures of the investigation (e.g., due to language problems, psychological disorders, etc.)

Date of first enrolment

01/02/2026

Date of final enrolment
01/05/2028

Locations

Countries of recruitment
Switzerland

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Sponsor information

Organisation
Hôpitaux Universitaires de Genève (HUG)

Funder(s)

Funder type

Funder Name
Hôpitaux Universitaires de Genève (HUG)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available