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# Non-invasive cardiac index monitoring in women during anaesthesia comparing the VenArt® device and transthoracic echocardiography

**Submission date**
01/10/2024

**Recruitment status**
No longer recruiting

**Registration date**
04/10/2024

**Overall study status**
Completed

**Last Edited**
08/01/2026

**Condition category**
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Cardiac output (CO) is an important determinant of both tissue oxygenation and blood pressure, which makes it essential to monitor during surgeries, when hemodynamics (blood flow) may vary due to the patient's state, the type of surgery and anesthetic drugs. Invasive techniques to measure cardiac output exist but are less frequently used now because of their higher risk of complications. The aim of this study is to determine whether the VenArt CO device, a non-invasive device, allows clinically acceptable values of cardiac output measurement in women undergoing a gynecological laparoscopic procedure under general anesthesia.

Who can participate?
Women aged 18 years or older undergoing general anaesthesia for a planned gynaecological laparoscopic procedure that is expected to last more than 60 minutes (combined anaesthesia and surgical time)

What does the study involve?
During the preparation for anesthesia, cardiac index will be measured using the VenArt CO device (which involves placement of a neck sensor on the external jugular vein and a pulse oximeter probe on one finger) and using transthoracic echocardiography (TTE). Comparison of these two values will be carried out at five different time points during the perioperative period.

What are the possible benefits and risks of participating?
Since this study will not change the usual state-of-the-art practice of anesthesia, it will not add any additional risk to the management of patients. The main benefit of this study will be to provide important information on the accuracy of the VenArt device in measuring CO in patients undergoing anesthesia for laparoscopic gynecological procedures in comparison with TTE. This knowledge will ultimately lead to a better understanding of how to treat patients during these procedures, especially during moments of hemodynamic instability.

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

When is the study starting and how long is it expected to run for?
August 2023 to October 2024

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

Who is the main contact?
Catherine Paschoud, catherine.paschoud@hug.ch

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Mrs Catherine Paschoud

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# Additional identifiers

### Protocol serial number
BASEC 2023-02000

# Study information

### Scientific Title
Non-invasive cardiac index monitoring in women during anaesthesia : a quantitative comparison of the VenArt® device based on Fick’s principle and transthoracic echocardiography

### Acronym
VenTTE

### Study objectives
The general hypothesis of this project is that the VenArt® CO device, based on a continuous Fick’s principle measuring non-invasively venous and arterial saturations, offers clinically acceptable data during laparoscopic interventions in adults without significant comorbidities. Specifically, it is hypothesized that the Mean Percentage Error (MPE), derived from the standard deviation (SD)

of the bias (i.e. the precision) between the two monitoring modalities and the mean cardiac index is inferior to 30.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 13/02/2024, Swiss Association of Research Ethics Committees (Rue Adrien-Lachenal 8, Geneva, 1207, Switzerland; +41 (0)22 546 51 01; ccer@etat.ge.ch), ref: 2023-02000

## Primary study design
Observational

## Study design
Single-centre prospective observational study

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Non-invasive cardiac index monitoring in women undergoing laparoscopic procedure under general anaesthesia

## Interventions
During the preparation for anaesthesia, two distinct measures of cardiac index will be extracted. Firstly, a small neck sensor will be placed in proximity to the external jugular vein and then a pulse oximeter probe will be placed on one of the fingers. Once a stable cardiac index has been obtained using the VenArt® CO device, transthoracic echocardiography (TTE) will also be performed to compare CI values.

Comparison of these two values will be carried out at five different timepoints during the perioperative period: before induction of general anaesthesia, after induction of general anaesthesia, before surgical incision, after insertion of 1st trocar and establishment of the capnoperitoneum (20 [mmHg]), and finally at least 10 minutes after reduction of the capnoperitoneum at 12 [mmHg] and table tilt (20-25° Trendelenburg).

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
VenArt® CO device

## Primary outcome(s)
Cardiac index values from the VenArt® CO device and transthoracic echocardiography measured simultaneously

## Key secondary outcome(s)

Cardiac index over time during the intraoperative course between the VenArt® CO device and transthoracic echocardiography. CO measures will be recorded at five different timepoints: before induction of general anaesthesia, after induction, before surgery, after pneumoperitoneum and finally after reduction of pneumoperitoneum and table tilt).

### Completion date
15/10/2024

## Eligibility

### Key inclusion criteria
1. 18 years old or older
2. Undergoing general anaesthesia for a planned gynaecological laparoscopic procedure that is expected to last more than 60 minutes (combined anaesthesia and surgical time)
3. Can understand and read French
4. American Society of Anesthesiologists (ASA) 1-3 status

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 Years

### Upper age limit
100 Years

### Sex
Female

### Total final enrolment
55

### Key exclusion criteria
1. Body mass index (BMI) >35 kg/m²
2. Any condition limiting the use of VenArt CO (according to the user manual, e.g. very restricted neck anatomy, abnormalities in peripheral saturations, known allergy to adhesive products [skin sensor], central vein stenosis, Reynaud's disease, severe COPD)
3. Any condition limiting the feasibility of TTE
4. Unplanned surgery (emergency)
5. Aortic regurgitation
6. Laparoscopie vNOTES procedure

### Date of first enrolment

04/04/2024

**Date of final enrolment**
15/10/2024

# Locations

**Countries of recruitment**
Switzerland

**Study participating centre**
**University Hospital of Geneva**
Rue Gabrielle-Perret-Gentil 4
Geneva
Switzerland
1205

# Sponsor information

**Organisation**
University Hospital of Geneva

**ROR**
https://ror.org/01m1pv723

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
University Hospital of Geneva

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study will be available upon request from Dr Catherine Paschoud (catherine.paschoud@hug.ch)

**IPD sharing plan summary**

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 17/12/2025 | 08/01/2026 | Yes | No |
| Participant information sheet | | | 03/10/2024 | No | Yes |
| Study website | | 11/11/2025 | 11/11/2025 | No | Yes |