

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/10/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/01/2026	Condition category Surgery	<input type="checkbox"/> 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

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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

Study design

Single-centre prospective observational study

Primary study design

Observational

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. Laparoscopic 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