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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
13/12/2024

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

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

Study website
https://recherche.hug.ch/

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See study outputs table

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

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

Primary outcome measure
Cardiac index values from the VenArt® CO device and transthoracic echocardiography measured simultaneously

Secondary outcome measures
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).

Overall study start date
21/08/2023

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
55

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
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Sponsor information

Organisation
University Hospital of Geneva

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://www.hug.ch

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of Geneva

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/05/2025

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?
Participant information sheet			03/10/2024	No	Yes