Corsano CardioWatch 287-2 for Improved E-health MOnitoring Evaluation Study.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON57542

Source
ToetsingOnline

Brief title
EMOC study

Condition

- Cardiac therapeutic procedures

Synonym
Cardiac surgery, Open heart surgery

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Comparative analysis, Corsano CardioWatch 287-2, E-health care pathway, Usability assessment

Outcome measures

Primary outcome

Primary outcomes

1. Mean difference and its SD (Standard Deviation) of the parameters measured including MEWS (Modified Early Warning Score) by the Corsano CardioWatch 287-2 and 'The Box'.

Secondary outcome

Secondary outcomes:

1. Mean difference and its SD of the Device User-Friendliness Comparison Survey between the Corsano CardioWatch 287-2 compared to 'The Box' in the E-health care pathway

2. Mean difference and its SD Usability of the Usability Assessment Survey between the Corsano CardioWatch 287-2 compared to 'The Box' in the E-health care pathway

Study description

Background summary

The research focuses on evaluating the Corsano CardioWatch 287-2 in comparison to 'The Box' within the E-health care pathway. While 'The Box' is a valuable and established tool for home measurements, it exhibits some limitations. The main areas for potential improvement are increasing user-friendliness for patients and usability for healthcare professionals. Therefore, the aim of this research is to assess whether the Corsano CardioWatch 287-2 can address these shortcomings, thereby enhancing the patient experience and health monitoring,

while retaining the valuable aspects of 'The Box'.

Study objective

The primary objective of the study is to compare the parameters detected by 'The Box' during the E-health care pathway with those detected by the Corsano CardioWatch 287-2.

The secondary objective is to evaluate the usability of the Corsano CardioWatch 287-2 compared to 'The Box' from the perspective of healthcare providers and the user-friendliness from the perspective of patients.

Study design

The study is a single-center, single-arm, two-phase study. Only one group of patients is approached for participation. The aim of the study is to compare conventional treatment and monitoring methods within the E-health care pathway with 'The Box' system in relation to the Corsano CardioWatch 287-2.

The study comprises two phases:

- **Phase 1:** Healthcare personnel do not have access to the data from the Corsano CardioWatch 287-2.
- **Phase 2:** Access to data is granted solely for feedback purposes without influencing clinical decisions.

In both phases, clinical data are retrospectively evaluated.

Three different analyses are performed:

1. Comparison of clinical parameters between the research device and the conventional BOX.
2. Comparison of user-friendliness for patients with a Device User-Friendliness Comparison Survey.
3. Comparison of usability for healthcare providers with a Usability Assessment Survey.

Study burden and risks

Burden for the Participants:
- Number of Questionnaires:Participants are required to complete only one short questionnaire regarding user-friendliness.
- Wearability:Patients are asked to wear the Corsano CardioWatch 287-2 throughout the study period. This device automatically measures vital parameters such as heart rate, respiratory rate, activity, sleep, SpO2, and body temperature. To obtain an ECG, patients need to press the watch for 30

seconds once a day.
- Study Location: The study takes place at a single center, namely the Leiden University Medical Center (LUMC).

Risks for the Participants:
- Physical Burden: The physical burden is minimal since patients only need to wear the watch and receive standard care according to the existing E-health care pathway.
- Side Effects:*No significant side effects or physical risks are expected from wearing the Corsano CardioWatch 287-2. The technology, such as photoplethysmography (PPG), uses low-energy green light which does not cause skin damage.
- Psychological Burden: There is no indication of psychological discomfort for the participants as the intervention is non-invasive and requires no additional medical procedures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

>= 18 years old;
able to provide consent.
following the peri-operative E-health care pathway
receiving open heart surgery

Exclusion criteria

Unable to wear the Corsano CardioWatch 287 due to reasons such as allergic reactions, wounds, amputations etc.;
Unable to receive blood pressure measurements per cuff due to lymphedema, amputation, dialysis shunt, wounds, etc.;
Pregnant women;
Breastfeeding women;
Unable or not willing to sign informed consent;
Significant mental or cognitive impairment.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	80
Type:	Anticipated

Medical products/devices used

Generic name:	Corsano CardioWatch 287-2
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-05-2025
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87003.058.24