Multiparameter vital signs monitoring validation of the Corsano CardioWatch 287-2

Published: 31-08-2022
Last updated: 06-04-2024

This study aims to validate the Corsano CardioWatch 287-2 for the continuous monitoring of heart rate at

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON51353

Source
ToetsingOnline

Brief title
MULTI-VITAL

Condition

- Coronary artery disorders

Synonym
angina pectoris, coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Corsano Health B.V.
Source(s) of monetary or material Support: Corsano Health BV

Intervention

Keyword: validation, vital signs, wearable, wristband

Outcome measures

Primary outcome

Root mean squared error between measurements (heart rate, RR-intervals, respiration rate, oxygen saturation, blood pressure) recorded by Corsano CardioWatch 287-2 and reference device.

Secondary outcome

Arithmetic mean and standard deviation of the error between blood pressure values measured by the Corsano CardioWatch 287-2 and the reference method according to ISO 81060-2:2018.

Study description

Background summary

Today, continuous monitoring of vital signs remains a challenge since it generally requires the patient to be connected to multiple wired sensors, which restricts patient mobility in the intra-mural setting and complicates home monitoring in the extra-mural setting. Wearable devices on the wrist, although emerging, are often not clinically validated or limited to the monitoring of one or two vital signs.

Study objective

This study aims to validate the Corsano CardioWatch 287-2 for the continuous monitoring of heart rate at <= 4 bpm root mean squared error (RMSE); interbeat intervals at <= 50 ms RMSE; breathing rate at <= 2 brpm RMSE; and peripheral oxygen saturation at <= 3 percentage point RMSE. Also, this study aims to validate the Corsano CardioWatch 287-2 for the measurement of non-invasive blood pressure according to ISO 81060-2:2018.

Study design

The study is a single center, single arm prospective study.
Summarizing, in patients being monitored intra-arterially, the Corsano CardioWatch 287-2 wristband will be placed on the patient*s wrist, enabling the comparison between wristband-data and data from routine monitoring. Measurements for the trial encompass standardized hemodynamic measurements. These consist of invasive and non-invasive blood pressure recordings, peripheral oxygen saturation, heart rate and respiration rate by a reference device.
In the catheterization room, measurements will be taken throughout the procedure (+/- 20 minutes) without intervening in the procedure itself. At three moments during the procedure, no actions will be performed for 60 seconds in order to get a clean measurement signal.

Study burden and risks

Patients will be asked for informed consent. If consent is provided, the patient will be put on the Corsano CardioWatch 287-2 during invasive arterial monitoring like heart catherization examination. Besides, the patient will be connected to sensors from a reference monitoring device. When the procedure is finished, the Corsano CardioWatch 287-2 and the sensors will be removed. There will be no follow-up.
The risks carried by this study are very low, considering the non-intrusiveness of the investigative device and the conventional sensors of the reference device. This study will not intervene in any medical intervention. In the heart catheterization room, during 3 moments of 60 seconds the procedure will be paused in order to obtain a clean measurement signal. The cardiologist will determine which moments are safest for this. In the intensive care unit, the measurements will always be subordinated to clinical interventions of the nurse or doctor. The measurements can be paused for any moment when this is requested by the nurse or doctor.
Study participants will have no direct benefit from participating to the trial. However, when the Corsano CardioWatch 287-2 has been validated, the patient population involved in this trial will benefit from a continuous monitoring device that is considerably less intrusive than conventional monitoring devices. This will facilitate long-term continuous intra- and extramural monitoring of vital signs.

Contacts

Public
Corsano Health B.V.

Wilhelmina van Pruisenweg 35
Den Haag 2595 AN

NL
Scientific
Corsano Health B.V.

Wilhelmina van Pruisenweg 35
Den Haag 2595 AN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• >= 18 years old;
• undergoing invasive monitoring, like coronary angiography;
• able to provide consent.

Exclusion criteria

Patients
• who cannot wear the Corsano CardioWatch 287 due to reasons such as allergic reactions, wounds, amputations etc.;
• unable or not willing to sign informed consent;
• with significant mental or cognitive impairment;
• who do not have a suitable entry site for the invasive arterial line.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-10-2022
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Corsano CardioWatch 287-2
Registration:	No

Ethics review

Approved WMO

Date:	31-08-2022
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	NL80236.000.22