Pulse Rate/SPO2/Respiration Rate/RR-intervals/Blood Pressure/Device Position Test for Corsano CARDIOWATCH 287-2 during High Intensity Interval Training: an Evaluation Study (HIIT-OXI-NIBP-POS)

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Ethical review	Approved WMO
Status	Completed
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON56499

Source
ToetsingOnline

Brief title
HIIT-OXI-NIBP-POS

Condition

- Cardiac arrhythmias

Synonym
n.v.t.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: evaluation, exercise, vital parameters, wearable

Outcome measures

Primary outcome

Root mean squared error between measurements (heart rate, SpO2 and respiration rate) recorded by Corsano Cardiowatch 87-2 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 81060-2:2019.

Study description

Background summary

In today's world, continuous monitoring of vital signs remains a challenge, as it generally requires patients to be connected to multiple wired sensors, which limits their mobility. Wearable wrist devices, although gaining popularity, are often not clinically validated or limited to monitoring one or two vital signs. The CardioWatch Bracelet is a remote monitoring system designed to continuously collect data in healthcare and home environments. CardioWatch 287-2 is a CE-certified medical device under EU-MDR conditions. It is capable of monitoring heart rate, heart rate variability (RR intervals), ECG, SpO2, respiration, body temperature, blood pressure, activity, and sleep.

Study objective

This study aims to evaluate the Corsano Cardiowatch 287-2 for heart rate, heart rate variability (RR intervals), oxygen saturation, respiratory rate, and blood pressure during strenuous activities such as High-Intensity Interval Training

(HIIT). Validation will be conducted for heart rate values with a root mean squared error (RMSE) of <= 4, respiratory rate with a RMSE of <= 2 breaths per minute (brpm), peripheral oxygen saturation with a RMSE of <= 3 percentage points, and blood pressure according to ISO 81060-2:2018 with a RMSE of <= 5 mmHg.

Study design

This study involves adult volunteers who have provided informed consent to participate in the research. Participants are asked to perform a High-Intensity Interval Training on a stationary bike (LifeSpan R3i), during which heart rate, heart rate variability, blood pressure, SpO2, and respiratory rate are measured. This is done using both CE-marked devices considered as the gold standard (Covidien Nellcor PM10N pulse oximeter, Bosh+Sohn Boso APBM blood pressure monitor, Vivalink ECG patch) and the CE-marked Corsano CardioWatch 287-2. Two initialization measurements are taken before the workout, with one measurement using the Corsano CardioWatch 287-2 at a 90-degree angle. Participation in the study takes approximately 20 minutes, and participants will not experience any inconvenience. The data is collected in Corsano's certified cloud, and the results will be compared afterward. The data is fully pseudonymized.

Study burden and risks

Participants will be asked for informed consent. If consent is granted, the participant will be connected to the Corsano Cardiowatch 287-2, Covidien Nellcor PM10N pulse oximeter, Bosh+Sohn Boso APBM blood pressure monitor, and Vivalink ECG patch during a High-Intensity Interval Training (HIIT) on a stationary bike for continuous monitoring and reference measurements. Once the procedure is completed, the Corsano Cardiowatch 287-2 and all other devices will be removed. There will be no follow-up.
The risks associated with this study are very low, given the non-intrusiveness of the research device and the conventional sensors of the reference devices. The Vivalink ECG patch may cause minor skin irritation.
Participants in the study will not receive any direct benefits from participating in the research.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

18 years old or above, able to provide consent, able to preform a HIIT

Exclusion criteria

Injuries or unable to perform HIIT, unable to wear the Corsano CardioWatch 287-2 due to reasons such as allergic reactions, wounds, amputations etc., unable to sign informed consent, baseline SBP > 160 mmHg and/or baseline DBP > 100 mmHg, high total cardiovascular risk, pregnant or breastfeeding.

Study design

Design

Study phase:	4
Study type:	Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	29-01-2024
Enrollment:	35
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	22-01-2024
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	NL85330.058.23