Remote Cardiac Monitoring by the Corsano CardioWatch 287-2 Evaluation Study

Published: 21-04-2023
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Primary objective: To compare the number of episodes of atrial fibrillation detected by the Corsano CardioWatch 287-2 during 28 days of use with the number of episodes of atrial fibrillation detected by conventional Holter monitoring during 48 hours...

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

Summary

ID

NL-OMON56059

Source
ToetsingOnline

Brief title
RECAMO study

Condition

- Cardiac arrhythmias
- Vascular hypertensive disorders

Synonym
atrial fibrillation; hypertension, high blood pressure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: atrial fibrillation, blood pressure, remote patient monitoring, wristband

Outcome measures

Primary outcome

Absolute percentage increase of patients in whom at least one event of atrial fibrillation is detected by the Corsano CardioWatch 287-2 during 28 days of monitoring, compared to a conventional EKG holter during 24-48 hours of monitoring.

Secondary outcome

(1) Mean blood pressure difference and its SD between blood pressure measured by the Corsano CardioWatch 287-2 and blood pressure measured by a conventional oscillometric blood pressure cuff.

(2) Usability of the Corsano CardioWatch 287-2 in a remote care setting as determined by a questionnaire.

(3) Difference between awake-asleep blood pressure change as measured by the Corsano CardioWatch 287-2 and awake-asleep blood pressure change as measured by a conventional 30-min. oscillometric blood pressure cuff across 24 hours.

Study description

Background summary

Wearables have the potential to monitor patients remotely. The Corsano CardioWatch 287-2 is such a medical device that can monitor atrial fibrillation and long-term blood pressure. The device has been validated using clinical trials in hospitals, but validation in the intended remote setting is lacking.

Study objective

Primary objective: To compare the number of episodes of atrial fibrillation detected by the Corsano CardioWatch 287-2 during 28 days of use with the number of episodes of atrial fibrillation detected by conventional Holter monitoring during 48 hours of use (standard care).
Secondary objective: To assess the difference in blood pressure measurements obtained by the Corsano CardioWatch 287-2 and the conventional cuff blood pressure monitor over a period of 28 days; to assess the usability of the Corsano CardioWatch 287-2 from a patient perspective; to assess the difference between awake-asleep blood pressure change as measured by the Corsano CardioWatch 287-2 and awake-asleep blood pressure change as measured by a conventional 30-min. oscillometric blood pressure cuff across 24 hours.

Study design

Group A:
Conventional 24 hour EKG holter monitoring will be compared to 28 day continuous monitoring by the Corsano CardioWatch 287-2 to assess whether the percentage of patients in whom atrial fibrillation is detected will increase. Detection of atrial fibrillation with the Corsano CardioWatch 287-2 is done by optical photoplethysmography (PPG), after which atrial fibrillation is confirmed with a 30-second ECG measurement.
Additionally, conventional cuff blood pressure will be compared to blood pressure measured by the Corsano CardioWatch 287-2 to validate free-living blood pressure monitoring. Patients will measure their blood pressure daily with a cuff blood pressure measurement device. The measurements at day 7, 14, 21 will be used to reinforce the Corsano blood pressure algorithm. The remaining measurements will be used to compare the blood pressure with the values measured by the Corsano CardioWatch 287-2 to assess accuracy.

Group B:
Conventional automatic cuff blood pressure measurement will be compared with the Corsano CardioWatch 287-2 for 24-48 hours. The automatic cuff blood pressure monitor will take a blood pressure reading every 30 minutes. Each reading will be compared with the Corsano CardioWatch 287-2 reading.

Study burden and risks

At the cardiologist's office, Group A and B patients receive 3 blood pressure measurements. These are performed by a nurse. Group A will take daily blood pressure readings of themselves at home. If atrial fibrillation is detected by the wristband, Group A patients will be asked to take an ECG. Finally, Group A patients will be asked once to complete a questionnaire. Group B only has to wear the wristband for 24 to 48 hours as an additional burden in addition to the aforementioned initial measurements.

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;
* receiving EKG holter or automatic blood pressure cuff for home monitoring per doctor prescription

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, dyalisis shunt, wounds, etc.;

* pregnant women;
* breastfeeding women;
* upper arm circumference not within the cuff range (22-42 cm)
* 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:	Recruiting
Start date (anticipated):	15-06-2023
Enrollment:	190
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	21-04-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	24-10-2023
Application type:	Amendment
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	NL83281.000.22